NOVEN PHARMACEUTICALS INC
Form 10-K
March 13, 2009

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

(Mark One)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2008

o **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission file number 0-17254
NOVEN PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**59-2767632**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
11960 S.W. 144 th Street, Miami, Florida	**33186**
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code 305-253-5099
Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, Par Value $.0001	**NASDAQ Global Select Market**

Securities registered pursuant to Section 12(g) of the Act: None
Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No þ
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No þ
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes o No þ
Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. þ
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o	Accelerated filer þ	Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes o No þ

The aggregate market value of the voting and non-voting common equity of the registrant held by non-affiliates of the registrant was approximately $266 million (computed by reference to the price at which the common equity was last sold on June 30, 2008, the last business day of the registrant s most recently completed second fiscal quarter).

As of March 2, 2009, there were 24,913,418 shares of Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III: Portions of the registrant s Proxy Statement for its 2009 Annual Meeting of Stockholders

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NOVEN PHARMACEUTICALS, INC.
Annual Report on Form 10-K
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EX-32.2

Trademark Information: DOT Matrix® and DentiPatch® are registered trademarks of Noven Pharmaceuticals, Inc.; Lithobid®, Pexeva® and Stavzor® are registered trademarks, and Mesafem is a trademark of Noven Therapeutics, LLC; Vivelle® is a registered trademark of Novartis Pharmaceuticals Corporation; Estradot® (foreign) and Vivelle-Dot® are registered trademarks, and Menorest is a trademark, of Novartis AG; CombiPatch® and Estalis® (United States) are registered trademarks of Vivelle Ventures LLC; Menoaid® is a registered trademark of Purapharm International; Femiest® is a registered trademark of sanofi-aventis in Japan; Daytrana® is a registered trademark of Shire Pharmaceuticals Ireland Limited; Intrinsa® is a trademark of P&G Pharmaceuticals; Duragesic® is a registered trademark of Johnson & Johnson Corporation; Ortho Evra® is a registered trademark of Ortho-McNeil Pharmaceutical, Inc.; Pristiq® is a registered trademark of Wyeth Laboratories or affiliates; and Vyvanse® is a registered trademark of Shire LLC.

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FORWARD-LOOKING INFORMATION

Statements in this report that are not descriptions of historical facts are forward-looking statements provided under the safe harbor protection of the Private Securities Litigation Reform Act of 1995. These statements are made to enable a better understanding of our business, but because these statements are subject to many risks, uncertainties, future developments and changes over time, actual results may differ materially from those expressed or implied by such statements. Examples of forward-looking statements are statements about anticipated financial or operating results, financial projections, business prospects, future product performance, future research and development results, anticipated regulatory filings and approvals and other matters that are not historical facts. Such statements often include words such as anticipates, believes, estimates, expects, intends, may, plans, could, should, seeks, will, would or similar expressions.

These forward-looking statements are based on the information that was available to us, and the expectations and assumptions that were deemed reasonable by us, at the time the statements were made. We do not undertake any obligation to update any forward-looking statements in this report or in any of our other communications, except as required by law, and all such forward-looking statements should be read as of the time the statements were made, and with the recognition that these forward-looking statements may not be complete or accurate at a later date.

Many factors may cause or contribute to actual results or events being materially different from those expressed or implied by forward-looking statements. Although it is not possible to predict or identify all such factors, they include those factors set forth under Risk Factors beginning on page 21 of this report.

PART I

Item 1. Business.

General Business & Strategy

Noven Pharmaceuticals, Inc. (we or Noven) is a specialty pharmaceutical company engaged in the research, development, manufacturing, licensing, marketing and sale of prescription pharmaceutical products. Our business is focused in three principal areas: (i) Noven Transdermals, our transdermal drug delivery segment; (ii) Novogyne Pharmaceuticals (Novogyne) our women s health joint venture with Novartis Pharmaceuticals Corporation (Novartis); and (iii) Noven Therapeutics, our specialty pharmaceutical segment. Each of these principal areas is more fully discussed below.

Our primary commercialized products include prescription transdermal patches utilizing our proprietary transdermal drug delivery technology for use in the treatment of Attention Deficit Hyperactivity Disorder (ADHD) and in menopausal hormone therapy (HT), as well as oral prescription products for use in the treatment of certain psychiatric conditions. Our developmental pipeline includes products in the women s health and central nervous system (CNS) categories.

Our long-term strategy for growth is focused on: (i) expanding and diversifying the transdermal product offerings of Noven Transdermals through new transdermal product development activities and new or expanded industry collaborations; (ii) maximizing the opportunities presented at our Novogyne joint venture by continuing effective promotion of Vivelle-Dot® and CombiPatch® and seeking to

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expand the range of products offered by the Novogyne sales force; and (iii) leveraging the marketing and sales infrastructure and industry expertise of Noven Therapeutics with specialty pharmaceutical products, and with complementary products that we will seek to develop or acquire, and possible strategic collaborations all with the goal of establishing Noven as a leading, high growth specialty pharmaceutical company. We regularly review our corporate strategies to evaluate their suitability and effectiveness in light of evolving business, industry, market and other conditions.

Noven operates in three segments distinguished along product categories and nature of the business unit: (i) Noven Transdermals, which currently engages in the manufacturing, licensing and sale to partners of prescription transdermal products; (ii) Novogyne, our women s health joint venture with Novartis in which we own a 49% equity interest and (iii) Noven Therapeutics, which currently engages in the marketing and sale of pharmaceutical products. Historically, Novogyne was viewed as a component of the Noven Transdermals unit because the joint venture s primary activity involves the marketing and sale in the United States and Canada of patches manufactured by Noven Transdermals. In the fourth quarter of 2008, as a result of management and organizational changes throughout 2008, Noven revised its presentation of reportable segments to reflect the joint venture as a reportable unit distinct from the manufacturing and licensing activities of Noven Transdermals. This view is consistent with the manner in which information is reported for management decision making. See Note 17 Segment and Customer Data in our Notes to Consolidated Financial Statements for Noven s segment financial reporting.

We were incorporated in Delaware in 1987 as Noven Pharmaceuticals, Inc., and our principal executive offices are located at 11960 S.W. 144th Street, Miami, Florida 33186. Our telephone number is (305) 253-5099, and our website address is www.noven.com.

Noven Transdermals

Our Noven Transdermals segment is engaged in the manufacturing, licensing and sale of advanced transdermal patches utilizing our proprietary drug delivery technologies. Our principal commercialized transdermal products are prescription patches for use in the treatment of ADHD and in HT. These products include:

Daytrana®, the first and only transdermal patch approved by the United States Food & Drug Administration (FDA) for the treatment of ADHD.

Vivelle-Dot®, the most prescribed transdermal estrogen therapy product in the United States and the smallest estrogen patch approved by the FDA. This product is marketed primarily under the brand name Estradot® outside the United States.

CombiPatch®, the first combination estrogen/progestin transdermal patch approved by the FDA. This product is marketed primarily under the brand name Estalis® outside the United States.

Transdermal patches utilize an adhesive patch containing medication that is administered through the skin and into the bloodstream over an extended period of time. Patches avoid first pass liver metabolism and may offer significant advantages over conventional oral and parenteral dosage forms, including non-invasive administration, controlled delivery, improved patient compliance, flexible dose duration and avoidance of certain side effects.

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Patches incorporating our patented DOT Matrix® technology, such as Daytrana®, Vivelle-Dot® and CombiPatch®, are diffusion-based patches that use a patented blend of silicone adhesive, acrylic adhesive and drug. DOT Matrix® is a highly efficient class of diffusion-based drug-in-adhesive patch technology, patented through 2014, that can often deliver more drug through a smaller patch area than competitive patches without using irritating skin permeation enhancers and without compromising adhesion. This patented blend of silicone adhesive, acrylic adhesive and drug causes microscopic pockets of concentrated drug to be formed and uniformly dispersed throughout the patch s drug/adhesive layer. The resulting high concentration gradient between each drug pocket and the skin works to enhance the diffusion of drug from the patch through the skin and into the bloodstream. This inherent delivery efficiency reduces the need for skin permeation enhancers. Precise ratios of silicone adhesive, acrylic adhesive and drug regulate the rate of drug delivery and help assure therapeutic blood levels over the intended course of therapy. We believe that our DOT Matrix® and other transdermal technologies enable us to develop patient-friendly transdermal systems that can reduce skin irritation sometimes associated with patches, improve adhesion, minimize patch size and improve patch appearance.

Novogyne Pharmaceuticals

Our HT products are marketed and sold in the United States through Vivelle Ventures LLC (d/b/a Novogyne Pharmaceuticals) (Novogyne), a joint venture that we established with Novartis in 1998 to market and sell women s prescription healthcare products. These products include our transdermal hormone therapy product delivery systems marketed under the brand names Vivelle-Dot® and CombiPatch®. We hold a 49% equity interest in Novogyne, and Novartis holds the remaining 51% equity interest.

Novogyne s sales and marketing efforts have helped Vivelle-Dot® to become the most prescribed product in the transdermal estrogen therapy (ET) patch category, with a 61% share of monthly total prescriptions written in the United States as of December 31, 2008. In connection with a transition to our advanced Vivelle-Dot® product, we ceased manufacturing our first generation estrogen patch (which was marketed as Vivelle®, Menorest and Femiest®) in late 2006.

Under the terms of the joint venture agreements, we manufacture and supply Vivelle-Dot® and CombiPatch® to Novogyne, perform marketing, sales and promotional activities, and receive royalties from Novogyne based on Novogyne s sales of Vivelle-Dot® and CombiPatch®. We are also reimbursed by Novogyne for costs incurred by us on behalf of Novogyne, including costs associated with the Noven employees who comprise the Novogyne sales force and other Noven personnel who provide services to Novogyne. Novartis distributes Vivelle-Dot® and CombiPatch® and provides certain other services to Novogyne, including contracting with the managed care sector and all regulatory, accounting and legal services.

We account for our investment in Novogyne under the equity method of accounting and report our share of Novogyne s earnings as Equity in earnings of Novogyne on our Consolidated Statements of Operations. We defer the recognition of 49% of our profit on products sold to Novogyne until the products are sold by Novogyne to third party customers. Under the terms of the joint venture agreements, Novartis is entitled to an annual $6.1 million preferred return from Novogyne, which has the effect of reducing our share of Novogyne s income in the first quarter of each year. After the annual preferred return to Novartis, our share of Novogyne s income increases as product sales increase, subject to a maximum of 49%. In 2008, 2007 and 2006, our share of Novogyne s income was $45.6 million, $35.9 million and $28.6 million,

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respectively, representing 48.9%, 48.6% and 48.4%, respectively, of Novogyne s income after Novartis preferred returns for each of those years. The income we recognize from Novogyne is a non-cash item. Any cash we receive from Novogyne is in the form of cash distributions which are based upon a contractual formula. Accordingly, the amount of cash that we receive from Novogyne in any period is typically not the same as the amount of income we recognize from Novogyne for that period. In 2008, 2007 and 2006, we received $42.0 million, $28.8 million and $26.4 million, respectively, in distributions from Novogyne, which accounted for a substantial portion of our net operating cash flows for these periods. We expect that for the next several years a substantial portion of our earnings and cash flows will be generated through our interest in Novogyne.

Novogyne is managed by a committee (the Management Committee) comprised of five members, three of whom are appointed by Novartis and two of whom are appointed by Noven. Noven s Executive Vice President is a Management Committee member and serves as President of Novogyne. Pursuant to the joint venture agreements, certain significant actions require a supermajority vote of the Management Committee members, including approving or amending the annual operating and capital budgets of Novogyne, incurring debt or guaranties in excess of $1.0 million, entering into new supply or licensing arrangements, marketing new products and acquiring or disposing of material amounts of Novogyne s assets. Novartis has the right to dissolve the joint venture in the event of a change in control of Noven if the entity which acquires control is one of the ten largest pharmaceutical companies (as measured by annual dollar sales). Upon dissolution, Novartis would reacquire the rights to market Vivelle-Dot® under the terms of the original license agreement with Novartis for Noven s transdermal estrogen patches, and Novogyne s other assets would be liquidated and distributed to the parties in accordance with their capital account balances. The joint venture will also dissolve upon the expiration of the original license agreement with Novartis for Noven s transdermal estrogen patches, as described below under Commercialized Products Hormone Therapy -Vivelle-Dot®/Estradot®.

The joint venture agreement includes a buy/sell provision that either Noven or Novartis may trigger by notifying the other party of the price at which the triggering party would be willing to acquire the other party s entire interest in the joint venture. Upon receipt of this notice, the non-triggering party has the option to either purchase the triggering party s interest in Novogyne or to sell its own interest in Novogyne to the triggering party at the price established by the triggering party. If we are the purchaser, then we must also pay an additional amount equal to the net present value of Novartis preferred return. This amount is calculated by applying a specified discount rate and a period of 10 years to Novartis $6.1 million annual preferred return.

Noven Therapeutics

In August 2007, we acquired Noven Therapeutics, which now comprises our specialty pharmaceutical operations. Noven Therapeutics currently markets and sells three branded prescription psychiatry products:

Stavzor®, a valproic acid delayed release product utilizing a proprietary enteric-coated soft gelatin capsule delivery system. In July 2008, the FDA granted final approval for the product, which is indicated for use in the treatment of manic episodes associated with bipolar disorder, monotherapy and adjunctive therapy in multiple seizure types (including epilepsy), and prophylaxis of migraine headaches. Stavzor® was commercially launched in August 2008.

Pexeva®, a selective serotonin re-uptake inhibitor (SSRI) antidepressant indicated for major depressive disorder, panic disorder, obsessive compulsive disorder and generalized anxiety disorder.

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Lithobid®, an extended release lithium product indicated for the maintenance of bipolar disorder and the treatment of related manic episodes.

In addition, we are advancing the development of Mesafem, a non-hormonal therapy in Phase 2 clinical studies for the treatment of vasomotor symptoms associated with menopause. We will seek to leverage Noven Therapeutics marketing and sales infrastructure with complementary products that we will seek to develop or acquire.

Products

The following table sets forth certain information regarding our commercialized products and products under development.

Product	Indication	Commercialized or Developmental	Regulatory Status
		Noven Transdermals	
Vivelle-Dot®/Estradot®	Menopausal symptoms/ osteoporosis	Commercialized	FDA-approved; Approved in multiple foreign countries
CombiPatch®/Estalis®/ Menoaid®	Menopausal symptoms/ osteoporosis	Commercialized	FDA-approved; Approved in multiple foreign countries
Daytrana®	ADHD	Commercialized	FDA-approved; Application filed in European Union, Canada
Amphetamine Patch	ADHD	Developmental	Currently undergoing Phase 1 study
Testosterone Patch	Hypoactive Sexual Desire Disorder and other indications	Developmental	Partner s NDA withdrawn in December 2004
		Noven Therapeutics	
Stavzor®	Bipolar disorder, migraine therapy and epilepsy	Commercialized	FDA-approved
Pexeva®	Major depressive disorder, panic disorder, obsessive compulsive disorder and generalized anxiety disorder	Commercialized	FDA-approved
Lithobid®	Bipolar disorder and related manic episodes	Commercialized	FDA-approved
Mesafem		Developmental	

	Vasomotor symptoms (hot flashes)		Currently undergoing Phase 2 study
	Transmucosal		
DentiPatch®	Dental pain associated with certain dental procedures	Commercialized	FDA-approved

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Commercialized Products

Hormone Therapy

Overview

Our menopausal HT products consist of:

Vivelle-Dot® /Estradot® our advanced transdermal estrogen patch; and

CombiPatch® /Estalis® /Menoaid® our combination transdermal estrogen/progestin patch.

Our HT products are indicated for menopausal symptoms. The most common acute physical symptoms of natural or surgical menopause are hot flashes and night sweats, which can occur in a substantial percentage of menopausal women. Another common symptom associated with menopause is vaginal dryness. Moderate-to-severe menopausal symptoms can be treated by replacing the estrogen that the body can no longer produce. Estrogen therapy can effectively relieve hot flashes and night sweats and can prevent drying and shrinking of the reproductive system. Our ET products are also indicated for the prevention of osteoporosis, a progressive deterioration of the skeletal system through the loss of bone mass. There are, however, other approved therapies for the prevention of osteoporosis, and our labeling advises that ET should be used for this condition only by women who have a significant risk of osteoporosis and for whom non-estrogen therapies are inappropriate. Although benefits of ET include menopausal symptom control and osteoporosis prevention, estrogen-only therapy has been associated with an increased risk of endometrial cancer for women who have an intact uterus (non-hysterectomized). To address this situation, a combination therapy of estrogen and progestin may be prescribed. Using both hormones together has been shown to reduce the risk of endometrial cancer while continuing to produce the menopausal symptom control benefits of ET.

Vivelle-Dot®/Estradot®

Utilizing our proprietary DOT Matrix® technology, our advanced transdermal estrogen patch (marketed as Vivelle-Dot® and Estradot®) is one-third the surface area of our previous Vivelle® estrogen patch at any given dosage level, yet provides the same delivery of drug over the same timeframe. This system is more flexible and comfortable to wear than the original product, with a lower potential for skin irritation. Vivelle-Dot® is the most prescribed transdermal ET product in the United States. This product is currently available in the United States in five dosage strengths, although the lowest dosage strength is approved only for prevention of osteoporosis.

In the United States and Canada, Noven has granted exclusive marketing rights for Vivelle-Dot® (and any follow-on transdermal estrogen patches) to Novogyne pursuant to a license agreement with Novartis that was subsequently assigned to Novogyne. The license agreement provides for Noven s receipt of royalty payments based upon sales. The license agreement is currently scheduled to expire in August 2014, co-terminus with the expiration of the patents for Vivelle-Dot®. The term of the license agreement will be extended for any follow-on transdermal estrogen patches subject to the agreement. Upon expiration, Novartis retains a perpetual, royalty-free, non-exclusive license to the product. Novogyne markets Vivelle-Dot® in the United States. In Canada, Vivelle-Dot® is marketed as Estradot® by an affiliate of Novartis Pharma AG (Novartis Pharma). Sanofi-aventis (Aventis) has marketing rights for Vivelle-Dot® in Japan. For all other countries, Novartis Pharma holds the rights to market this product under the name Estradot®, as well as any product improvements and future generations of estrogen patches developed by us. Under the terms of our license to Novartis Pharma, Novartis Pharma is responsible for seeking approval to market Estradot® in its territories. The product has been approved for marketing in over 30 foreign countries and Novartis Pharma has launched the product in multiple international markets.

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Pursuant to license and supply agreements with Novartis Pharma and Novogyne, we manufacture the product for these parties and receive fees based on their sales of the product. The supply agreement for the Estradot® product is a long-term agreement. The supply agreement for Vivelle-Dot® expired in January 2003. Since the expiration of this agreement, the parties have continued to operate in accordance with certain of the supply agreement s pricing terms.

CombiPatch®/Estalis®/Menoaid®

We developed the first combination transdermal HT system approved for marketing by the FDA (marketed as CombiPatch®, Estalis® and Menoaid®), a combination patch containing estradiol and norethindrone acetate, a progestin.

Novogyne acquired marketing rights to the product in 2001 from Aventis (which was then our exclusive worldwide licensee for the product) and markets the product under the brand name CombiPatch® in two dosage strengths in the United States. Novartis Pharma holds the right to market this product outside of the United States and is marketing this product under the brand name Estalis® in a number of foreign countries. The product is marketed in Japan under the brand name Menoaid® by a sublicensee of Aventis.

Pursuant to license and long-term supply agreements with Novartis Pharma, we manufacture the combination product for Novartis Pharma and receive fees based on their sales of the product. We sell the product to Novogyne at an agreed-upon price pursuant to a supply agreement.

The HT Product Market

We currently derive a significant portion of our revenues and substantially all of our net income from our HT products. Our total HT-related net revenues were $52.3 million, $45.6 million and $42.7 million for 2008, 2007 and 2006, respectively, which represented 48%, 55% and 70%, respectively, of our net revenues in each of those years.

Since 2002, several studies, including the Women s Health Initiative (WHI) study performed by the National Institutes of Health (NIH) and a study performed by the National Cancer Institute (NCI), have identified increased risks from the use of HT, including increased risks of invasive breast cancer, ovarian cancer, stroke, heart attacks and blood clots. As a result of the findings from these and other studies, the FDA has required that black box labeling be included on all HT products marketed in the United States to warn, among other things, that these products have been associated with increased risks for heart disease, heart attacks, strokes and breast cancer and that they are not approved for heart disease prevention. Since the July 2002 publication of the WHI and NCI study data, total United States prescriptions have declined for substantially all HT products, including our HT products in the aggregate. For a discussion of prescription trends for our products, see Management s Discussion and Analysis of Financial Condition and Results of Operations Executive Summary. Researchers continue to analyze data from the WHI study and other studies. Other studies evaluating HT are currently underway or in the planning stage. In particular, a private foundation has commenced a five-year study aimed at determining whether ET use by women aged 42 to 58 reduces the risk of heart disease. The study also seeks to determine if transdermal estrogen patches are more or less beneficial than an oral HT product. While our HT products are not being used in the study, the market for our HT products could be adversely affected if this study finds that a transdermal estrogen patch is less beneficial than other dosage forms, and we could be subject to increased product liability risk if HT patch products are found to increase the risk of adverse health consequences. Noven s HT products have been named in lawsuits filed against

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Noven, Novogyne and Novartis. See Note 19 Commitments and Contingencies Litigation, Claims and Assessments, in our Notes to Consolidated Financial Statements.

ADHD Therapy

Overview

ADHD is characterized by developmentally inappropriate levels of attention, concentration, activity, distractibility, hyperactivity and impulsivity symptoms. The disorder typically causes functional impairment that can limit success and create hardship in school and in social and familial relationships. As children age, the symptoms can lead to serious conduct disorders, criminal behavior, substance abuse and accidental injuries.

Daytrana®

We have developed a once-daily transdermal methylphenidate patch called Daytrana® for the treatment of ADHD. Daytrana® is the first and only transdermal medication approved to treat the symptoms of ADHD and is approved for children aged six to twelve years. The FDA approved Daytrana® in April 2006. The product combines the active ingredient methylphenidate with our DOT Matrix® technology and is designed to provide continuous release of medication throughout the day.

Presently, all ADHD medications approved in the United States (other than Daytrana®) are delivered orally. Stimulant therapies, including methylphenidate, which is designated as a Schedule II controlled substance by the United States Drug Enforcement Administration (DEA), are the most prescribed drug class for the treatment of ADHD. We believe that, among other advantages Daytrana® possesses as compared to certain oral ADHD medications, Daytrana® provides physicians and parents with broad dosing flexibility because dosing can be controlled by removing the patch earlier than the end of the nine hour wear time.

Shire, the market leader in the ADHD therapeutic category, is the exclusive, global licensee of Daytrana® pursuant to a license agreement established between Noven and Shire in 2003. Under the license agreement, we granted Shire the exclusive global rights to market Daytrana® in exchange for milestone payments to us of up to $150.0 million, all of which have been received. We are currently deferring and recognizing these milestone payments as license revenues on a straight-line basis, beginning on the date each was achieved through the first quarter of 2013, which is our current best estimate of the end of the useful economic life of the product.

Because we have received all milestone payments under the license agreement, Shire s obligations under the license agreement to promote Daytrana® and refrain from selling any other methylphenidate product have expired. Noven and Shire are also parties to a supply agreement under which we manufacture and supply Daytrana® to Shire at a fixed price. In 2008, our product sales of Daytrana® to Shire were $10.8 million. The supply agreement gives Shire the right to qualify a second manufacturing source and purchase a portion of its requirements from that source. If Shire were to exercise this right, our sales of Daytrana® to Shire would be adversely affected.

Noven and Shire have received reports from some consumers concerning the difficulty of removing the release liner from certain Daytrana® patches. In the first quarter of 2007 we, together with Shire, implemented enhancements to the Daytrana® release liner. In July 2007 we received a list of observations on Form 483 from the FDA following an inspection of our manufacturing facilities and the majority of these

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observations related to the Daytrana® patch and difficulties in removing the product s release liner, including certain product lots that utilized an enhanced release liner. In January 2008, we received a warning letter from the FDA citing deficiencies in the peel force specifications for Daytrana®.

In January 2009, we received from the FDA a list of observations on Form 483 following an on-site inspection of our manufacturing facilities. Like the warning letter and the prior Form 483, the majority of the observations in the Form 483 relate to the manufacture of Daytrana® product that exhibits high peel force characteristics, an issue which Noven and Shire continue to work to resolve.

During 2007 and 2008, Shire initiated voluntary market recalls (two in each year) of a portion of the Daytrana® product on the market primarily in response to feedback from patients and caregivers who continued to experience difficulty removing the release liner from some Daytrana® patches. In February 2008, we paid Shire $3.3 million related to the 2007 recalls and in November 2008, we paid Shire $3.7 million related to the 2008 recalls.

In the fourth quarter of 2008, we implemented new product release testing intended to predict which Daytrana® lots are at risk of developing peel force issues during the product s shelf life. Although the new release testing is designed to reduce the likelihood that newly-manufactured product will be withdrawn or recalled in the future, we cannot assure that our testing procedures will detect all production issues or that there will not be future Daytrana® market withdrawals or recalls. A more detailed discussion of the Daytrana® peel force issue and the associated financial impact can be found under the heading Certain Items that May Affect Historical or Future Comparability Daytrana® in Management s Discussion and Analysis of Financial Condition and Results of Operations.

We believe we have identified the root cause of the peel force issue. Noven is testing manufacturing solutions designed to address the peel force issue. Implementation of the solutions being tested will require prior agreement from the FDA. Subject to FDA review and agreement, Noven s current plan calls for shipments to Shire in the third or fourth quarter of 2009. We cannot assure that the FDA will approve the solutions being tested on a timely basis or at all. Noven s warning letter remains under review by the FDA.

Psychiatry Products

Our commercialized prescription psychiatry products consist of Stavzor®, a valproic acid delayed release product, Pexeva®, an SSRI antidepressant and Lithobid®, an extended release lithium product, all of which are oral products. We market and sell these products through the Psychiatry/CNS marketing and sales infrastructure of Noven Therapeutics. These products are manufactured by third parties and supplied to us under manufacturing and supply agreements.

Stavzor®

In July 2008, the FDA granted final approval for Stavzor®, which was commercially launched in August 2008. Stavzor® is a valproic acid delayed release product that utilizes a proprietary enteric-coated soft gelatin capsule delivery system. This product is indicated for use in the treatment of manic episodes associated with bipolar disorder, monotherapy and adjunctive therapy in multiple seizure types (including epilepsy), and prophylaxis of migraine headaches. Stavzor® competes with Abbott Laboratories Depakote® product and its generic equivalents.

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Noven Therapeutics is party to a development, license and supply agreement with Banner Pharmacaps Inc. (Banner), the exclusive manufacturer and supplier of the product. In consideration for certain license and development rights granted by Banner under the agreement, we are obligated to make certain potential future payments, including escalating royalties on future sales.

Pexeva®

Pexeva® is an SSRI antidepressant indicated for major depressive disorder, panic disorder, obsessive compulsive disorder and generalized anxiety disorder. This product is one of only two remaining patented brands without a generic equivalent in the United States SSRI market. Pexeva® is subject to a composition of matter patent that extends to 2017, as well as other patents that extend to 2022.

Noven Therapeutics acquired Pexeva® from Synthon Pharmaceuticals, Inc. (Synthon) in November 2005. In this transaction, Noven Therapeutics purchased certain assets related to Pexeva®, including the New Drug Application (NDA), intellectual property (including patents and trademarks) and certain finished goods inventory. The purchase of Pexeva® included a cash payment at the time of closing and an obligation to make certain future fixed payments and possible future contingent milestone payments of up to $11.5 million in the event sales of Pexeva® or any other products based on the same compound as is used in Pexeva® achieve specified levels. We accrued for these contingent payments at the time of closing of the Noven Therapeutics transaction. We became obligated to pay $6.5 million of such milestones based on sales of Pexeva® in 2007 and 2008. In 2008, we recognized $5.0 million in operating income as a result of the reversal of the remaining accrued liability upon our determination that the achievement of the remainder of the contingent milestone was no longer probable based on projected sales of Pexeva®. However, we remain contingently liable for the $5.0 million payment if annual net sales of a future product utilizing the same compound as is used in Pexeva® achieves $30.0 million or more through 2017.

Lithobid®

Lithobid®, an extended release lithium product, is the only branded lithium product sold in the United States. This product is indicated for the maintenance of bipolar disorder and the treatment of related manic episodes.

Noven Therapeutics acquired Lithobid® from Solvay Pharmaceuticals, Inc. (Solvay) in August 2004. In this transaction, Noven Therapeutics purchased certain assets related to Lithobid® including the NDA, intellectual property (including trademarks) and certain finished goods inventory. ANI Pharmaceuticals, Inc. (ANI) manufactures Lithobid® under a manufacturing and supply agreement with Noven Therapeutics.

Transmucosal Product

DentiPatch®, approved in 1996 and launched in 1997, was the first FDA-approved oral transmucosal patch. Sales of DentiPatch® are not material to our consolidated results of operations and we intend to discontinue the product once current inventory is exhausted, which we expect to occur during 2009.

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Products Under Development

Research and Development

Transdermal Products

Our long-term prospects are dependent upon the successful development and commercialization of new products. Noven s research and development program investigates and seeks to identify compounds that can be delivered transdermally which we believe may have substantial clinical utility and market potential, as well as transdermal products that we believe can be improved by using our patented technologies. We typically seek to develop transdermal products that use approved drugs that currently are being delivered to patients through means other than transdermal delivery, but we may also explore new formulations or proprietary products where we believe our transdermal technology may be beneficially applied. As part of our transdermal development strategy, we seek to supplement our research and development efforts by entering into research and development agreements, joint ventures and other collaborative arrangements with other companies. We have entered into several early stage feasibility and/or development agreements with other pharmaceutical companies to determine the feasibility of transdermal delivery of various compounds.

Mesafem

As part of the Noven Therapeutics acquisition, we acquired a women s health product called Mesafem that, if successfully developed and approved, would complement our expertise in the women s health area. Mesafem is a low-dose paroxetine mesylate capsule under development for the treatment of vasomotor symptoms associated with menopause, including hot flashes and night sweats (VMS). Published clinical data has demonstrated the efficacy of paroxetine for this indication. Mesafem is subject to the same patents as Pexeva®, as well as other pending patent applications, and may benefit from three years of market exclusivity under the Hatch-Waxman Act. As of the date of this report, Mesafem is in Phase 2 clinical studies.

If successfully developed and approved, Mesafem would provide women with an alternative to HT products for VMS. It would participate in a new market segment that is expected to include Pristiq®, a product under development by Wyeth Pharmaceuticals for VMS. We estimate that over 20 million women in the United States are affected by VMS and, of that number, only about 5 million are under treatment for the condition.

Lithium QD and Stavzor® ER

Following an internal review and rationalization of projects in our drug development pipeline, we discontinued development of our Lithium QD and Stavzor® ER projects in November 2008.

For the years ended December 31, 2008, 2007 and 2006, our research and development expense was $15.5 million, $14.0 million (excluding acquired in-process research and development) and $11.5 million, respectively. To bring Mesafem to market, we plan to increase our research and development expense significantly over the next several years. See Management s Discussion and Analysis of Financial Condition and Results of Operations Outlook.

Our research and development expense may vary significantly from quarter to quarter depending on product development cycles, the

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timing of clinical studies and whether we are or a third party is funding development. We intend to focus on long-term growth prospects and, therefore, may incur higher than expected research and development expenses in a given period rather than delay clinical activities. These fluctuations in research and development spending may not be accurately anticipated and may have a material effect on our results of operations.

Transdermal Product Development Collaborations

Amphetamine Transdermal System

On November 5, 2008, we entered into a letter agreement (the Termination Agreement) with Shire terminating our agreements with Shire for the development of an amphetamine patch for ADHD. Under the Termination Agreement, rights to the developmental amphetamine patch were returned to us and we intend to pursue the further development and commercialization of the product. Shire will be entitled to a modest royalty if we elect to commercialize a product that incorporates intellectual property arising from the development project with Shire. As a result of the termination of this project with Shire, we recognized $7.2 million of previously deferred license and contract revenues in the fourth quarter of 2008.

Transdermal System for HSDD

In April 2003, we established a collaboration with Procter & Gamble Pharmaceuticals, Inc. (P&GP) relating to the development and commercialization of prescription transdermal patches for the treatment of Hypoactive Sexual Desire Disorder (HSDD) in women. The products under development explore follow-on product opportunities for Intrinsa®, P&GP s in-licensed investigational transdermal testosterone patch designed to help restore sexual desire in menopausal women diagnosed with HSDD.

In August 2008, we entered into global license and supply agreements with P&GP, which supersede and replace the prior development letter agreement entered into between Noven and P&GP in April 2003. Under the agreements, we granted P&GP an exclusive worldwide license to our low-dose testosterone patch for use by women for HSDD and other indications, as well as potential next-generation patches, and P&GP granted us exclusive supplier rights with respect to such licensed products. If the testosterone patch is ultimately approved and commercially launched, we would receive royalties and manufacturing fees under the agreements. We may also receive additional contingent development and sales milestone payments related to the licensed products. The royalty payments are to be determined based on a percentage of P&GP s quarterly sales of the licensed products. The milestone payments are contingent upon the achievement of certain sales milestones. Pursuant to the agreements, P&GP will fund any clinical development costs and will be responsible for any regulatory filings and marketing applications associated with any licensed products developed under the agreements.

Competition

General

The markets for our products are highly competitive. Competition in the pharmaceutical industry is generally based on a company s marketing strength, product performance characteristics (i.e., reliability, safety, patient convenience) and product price. Acceptance by physicians and other health care providers, including managed care groups, is also critical to the success of a product. The first product on the market in a particular pharmaceutical area typically is able to obtain and maintain a significant market share for a period of time. In a highly

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competitive marketplace and with evolving technology and medical science, there can be no assurance that additional product introductions or medical developments by others will not render our products or technologies noncompetitive or obsolete or cause them to fall out of favor with physicians. Most of our competitors are substantially larger and have greater resources and larger sales forces than we have, as well as greater experience in developing and commercializing pharmaceutical products. Additionally, manufacturers of generic products typically do not bear significant research and development or education and marketing development costs and, consequently, may be able to offer their products at considerably lower prices than we are able to offer our products.

Competition Relating to Our Transdermal Products

All transdermal drug delivery products that we are developing may face competition from conventional forms of drug delivery (i.e., oral and parenteral), from alternate forms of drug delivery, such as controlled release oral delivery, gels and creams and possibly from alternate non-drug therapies. Some or all of the transdermal products being marketed or developed by us face, or will face, competition from other transdermal products that deliver the same or alternative drugs to treat the same indications.

As a general matter, transdermal drug delivery systems are more expensive and difficult to manufacture than oral formulations. We also compete with other drug delivery companies in the establishment of business arrangements with large pharmaceutical companies to assist in the development or marketing of products. It is also possible that Daytrana®, Vivelle-Dot® or our other products could, prior to the expiration of the applicable patent periods, face competition from a generic product if approved through the ANDA process or from a functionally-equivalent product that avoids infringing our patents.

Daytrana® participates in a highly competitive market for the treatment of ADHD, with a product mix that includes generic oral methylphenidate, long-acting formulations, other stimulant medications, medications not containing Schedule II controlled substances and a variety of other drug types. Shire currently markets products for the treatment of ADHD that compete with Daytrana®. We cannot assure that Shire will continue to market Daytrana® aggressively or effectively.

In the market for HT products, Novogyne competes against Wyeth Pharmaceuticals, Watson Pharmaceuticals, Inc., Mylan Pharmaceuticals, Inc., Berlex Laboratories, Allergan, Inc., Ascend Therapeutics, Inc., Barr Pharmaceuticals, Inc. and others, including Novartis, Novartis Pharma and their affiliates. We expect increased competition in the HT market as new and innovative products continue to be introduced in this field, including products using alternative delivery systems such as gels, creams and sprays, lower-dosage products and products that may be used to treat menopause-related symptoms that are not hormone-based or that may reduce the risks related to hormone-based products.

Competition Facing Noven Therapeutics

Pexeva® participates in the highly competitive United States SSRI market. In this market, we compete against, among others, Lilly, GlaxoSmithKline plc (GlaxoSmithKline) and Pfizer Inc. (Pfizer). In addition, although there is no approved generic equivalent to Pexeva®, it competes with generic versions of similar products with identical therapeutic profiles. We also compete in the United States SSRI market against manufacturers of emerging antidepressants, such as norepinephrine re-uptake inhibitors, substance P antagonists and CRF receptor antagonists.

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In the market for the treatment of manic episodes associated with bipolar disorder, Lithobid® competes against, among others, an AB-rated generic equivalent product, products marketed by Lilly, GlaxoSmithKline and AstraZeneca PLC (AstraZeneca), as well as generic versions of other lithium products and antiepileptic and antipsychotic agents.

Also in the market for the treatment of manic episodes associated with bipolar disorder, as well as monotherapy and adjunctive therapy in multiple seizure types (including epilepsy), and prophylaxis of migraine headaches, Stavzor® competes against, among others, Abbott Laboratories Depakote® product and its generic equivalents.

Dependence on Licensees and the Novogyne Joint Venture

During 2008, 27%, 34%, and 13% of our revenues were attributable to Novogyne, Shire and Novartis Pharma (and its affiliates), respectively, and our profitability has been significantly dependent on our equity in Novogyne s earnings, a non-cash item. Going forward, we expect to be dependent on sales to Novogyne, Shire and Novartis Pharma and other collaboration partners, as well as fees, amortization of previously received milestone payments, profit sharing and royalties generated from their sales of our transdermal delivery systems, for a significant portion of our expected revenues. No assurance can be given regarding the amount and timing of such revenues. Failure of these parties to successfully market our transdermal products would cause the quantity of such products purchased from us and the amount of manufacturing revenues, fees and royalties ultimately paid to us to be reduced and would therefore have a material adverse effect on our business and results of operations. We expect to be able to influence the marketing of Vivelle-Dot® and CombiPatch® in the United States through our participation in the management of Novogyne, but the Management Committee of Novogyne is comprised of a majority of Novartis representatives, and we will not be able to control those matters. While our agreements with our marketing partners may impose certain obligations on them, there can be no assurance that such agreements will provide us with any meaningful level of protection or cause these companies to perform at a level that we deem satisfactory. Further, these companies and their affiliates sell competing products, both in the United States and abroad, and it is possible that they will promote their competitive products to our detriment. Any reduction in the level of support and promotion that these companies provide to our products, whether as a result of their focus on other products or otherwise, could have a material adverse effect on our business, results of operations, financial condition and prospects.

Manufacturing

We manufacture our transdermal products. Our headquarters and transdermal manufacturing facility are located on a 15-acre site in Miami-Dade County, Florida. On this site, we conduct our manufacturing operations in a single facility comprised of two approximately 40,000 square foot buildings. We have supplemented our manufacturing facilities on our existing site with leased space located in close proximity to our existing site for the storage and, if necessary, the manufacture of new transdermal products.

Some raw materials essential to our transdermal business are readily available from multiple sources. Certain raw materials and components used in manufacturing our transdermal products (including essential polymer adhesives and other critical components) are, however, available from limited sources, and in some cases, a single source. In addition, the DEA controls access to controlled substances (including methylphenidate and amphetamine), and we must receive authorization from the DEA to obtain these substances. Any curtailment in the availability of such raw materials could result in production or other delays and, in the case of transdermal products for which only one raw

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material supplier exists, could result in a material loss of sales with consequent adverse effects on our business and results of operations. In addition, because most raw material sources for transdermal patches must generally be approved by regulatory authorities, changes in raw material suppliers may result in production delays, higher raw material costs and loss of sales, customers and market share. Some raw materials used in our transdermal products are supplied by companies that restrict certain medical uses of their products. While our use is presently acceptable, there can be no assurance that such companies will not expand their restrictions to include our applications.

Pursuant to manufacturing and supply agreements, we rely upon third party manufacturers to manufacture and supply us with Stavzor®, Pexeva® and Lithobid®. We depend on these third party manufacturers to perform their obligations in a timely manner and in accordance with applicable governmental regulations and their agreements with us. Additionally, we have no control over whether third party manufacturers breach their agreements with us or whether they determine to terminate or decline to renew agreements with us. Certain third party agreements prevent us from qualifying a second source of supply. Even where we are permitted to qualify a second source of supply, we expect it will be difficult and potentially costly and time-consuming for us to qualify a second source of product supply if necessary. Any interruption in our ability to obtain product supply and sell our products could adversely affect our present and future sales margins, market share and product pipeline, as well as harm our overall business.

As discussed above under ADHD Therapy Daytrana®, we are working to address certain manufacturing-related issues associated with the Daytrana® product.

Marketing and Sales

We maintain two sales forces a psychiatry/CNS sales force in support of Noven Therapeutics products, and a women s health sales force that we manage on behalf of our Novogyne joint venture. In general, we rely on industry partners to market and sell products developed by Noven Transdermals, although we may retain rights to certain of those products for marketing and sale by Noven.

At Noven Therapeutics, we maintain a targeted specialty sales force comprised of approximately 70 sales representatives and related marketing and sales infrastructure in support of our Stavzor®, Pexeva® and Lithobid® products.

On behalf of our Novogyne joint venture, we maintain and manage an approximately 120-person women s health sales force and related sales and marketing infrastructure in support of our Vivelle-Dot® and CombiPatch® products. In general, Noven s costs associated with these employees and substantially all of our sales and marketing activities conducted on behalf of Novogyne are reimbursed by Novogyne. Under the Novogyne joint venture agreements, Novartis has responsibility for Novogyne s distribution function (including managing the relationships and agreements with wholesale drug distributors and other trade customers) and its managed care strategy and relationships. We believe the expertise we have established in women s health through Novogyne may benefit the commercialization of Noven Therapeutics Mesafem product for menopausal vasomotor symptoms, if Mesafem is ultimately approved and marketed.

At Noven Transdermals, our strategy has historically been to retain manufacturing rights and to rely on collaborative partners with the marketing and sales resources necessary to broadly commercialize the products under development. This reflects the fact that our

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transdermal products in development are generally not focused in a single therapeutic category and therefore cannot be effectively addressed by a single sales force. Our growth strategy includes the possibility that we may retain all rights to a new transdermal product, and develop, market and sell it ourselves, particularly if it is aligned with the therapeutic focus of Noven Therapeutics.

Patents and Proprietary Rights

We seek to obtain patent protection on our delivery systems and manufacturing processes whenever possible. We have obtained 35 United States patents and over 350 foreign patents relating to our transdermal and transmucosal delivery systems and manufacturing processes, and have over 150 pending patent applications worldwide. As a result of changes in United States patent law under the General Agreement on Tariffs and Trade and the accompanying agreement on Trade-Related Aspects of Intellectual Property Law, the terms of some of our existing patents have been extended beyond the original term of 17 years from the date of grant. Our patents filed after June 7, 1995 will have a term of 20 years beginning on the effective filing date.

We are unaware of any challenge to the validity of our patents that could have a material adverse effect on our business or prospects. Other than the allegations made by Johnson-Matthey in the matter discussed in Note 19 Commitments and Contingencies Litigation, Claims and Assessments in the Notes to our Consolidated Financial Statements, we are unaware of any third party claim of patent infringement with respect to any of our products that could have a material adverse effect on our business and prospects.

Government Regulation

Our operations are subject to extensive regulation by governmental authorities in the United States and other countries with respect to the development, testing, approval, manufacturing, labeling, marketing and sale of pharmaceutical products, and the possession and use of controlled substances. We devote significant time, effort and expense to address the extensive government regulations applicable to our business.

The marketing of pharmaceutical products requires the approval of the FDA in the United States. The FDA has established regulations, guidelines and safety standards that apply to the pre-clinical evaluation, clinical testing, manufacturing and marketing of pharmaceutical products. The process of obtaining FDA approval for a new product may take several years or more and is likely to involve the expenditure of substantial resources. The steps required before a product can be produced and marketed for human use typically include: (i) pre-clinical studies; (ii) submission to the FDA of an Investigational New Drug Application (IND), which must become effective before human clinical trials may commence in the United States; (iii) adequate and well controlled human clinical trials that demonstrate reasonable assurance of the safety and efficacy of the product; (iv) submission to the FDA of an NDA; and (v) review and approval of the NDA by the FDA. Approval of a product by the FDA does not guarantee the product s safety or efficacy.

An NDA generally is required for products with new active ingredients, new indications, new routes of administration, new dosage forms or new strengths. An NDA requires that complete clinical studies of a product s safety and efficacy be submitted to the FDA, the cost of which is substantial. These costs can be reduced, however, for delivery systems that utilize already approved drugs. In these cases, the company seeking approval may refer to safety and toxicity data reviewed by the FDA in its approval process for the innovator product. In addition, a supplemental NDA may be filed to add an indication or make product improvements to an already approved product.

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An abbreviated approval process may be available for products that have, among other requirements, the same active ingredient(s), indication, route of administration, dosage form and dosage strength as an existing FDA-approved product covered by an NDA, if clinical studies have demonstrated bio-equivalence of the new product to the FDA-approved product covered by an NDA. For this abbreviated process, an ANDA is submitted to the FDA instead of an NDA. Under the FDA s ANDA regulations, companies that seek to introduce an ANDA product must also certify that the product does not infringe on any approved product s patent listed with the FDA or that such patent has expired. If the applicant certifies that its product does not infringe on the approved product s patent or that such patent is invalid, the patent holder may institute legal action to determine the relative rights of the parties and the application of the patent. Under the Hatch-Waxman Act, the FDA may not finally approve the ANDA until the earlier of 30 months after the date of the legal action or a final determination by a court that the applicable patent is invalid or would not be infringed by the applicant s product. We are developing products for which we or a licensee may file an ANDA.

Pre-clinical studies are conducted to obtain preliminary information on a product s safety. The results of these studies are submitted to the FDA as part of the IND and are reviewed by the FDA before human clinical trials can begin. Human clinical trials may commence 30 days after receipt of the IND by the FDA, unless the FDA objects to the commencement of clinical trials.

Human clinical trials are typically conducted in three sequential phases prior to FDA approval, but the phases may overlap. Phase 1 trials consist of testing the product primarily for safety and dosage strength in healthy volunteers or a small number of patients at one or more doses. In Phase 2 trials, the safety and efficacy of the product are evaluated in a patient population somewhat larger than the Phase 1 trials, generally at differing dosages. Phase 3 trials typically involve additional testing for safety and clinical efficacy in an expanded population at a number of separate clinical test sites. Phase 4 trials may be required after a product is already approved and on the market to learn more about the product s long-term risks, benefits and optimal use, or to test the product in different populations of people, such as children or adults. A clinical plan, or protocol, accompanied by information on the investigator(s) conducting the trials, must be submitted to the FDA prior to commencement of each phase of the clinical trials.

The results of product development and pre-clinical and clinical studies are submitted to the FDA as an NDA or ANDA for approval. If an application is submitted, there can be no assurance that the FDA will complete its review and approve the NDA or ANDA in a timely manner. The FDA may deny an NDA or ANDA if applicable regulatory criteria are not satisfied, or it may require additional clinical testing. Even if such data is submitted, the FDA may ultimately deny approval of the product. Further, if there are modifications to the drug, including changes in indication, dosage, manufacturing process, labeling, or a change in manufacturing facility, an NDA or ANDA notification may be required to be submitted to the FDA and FDA approval required prior to implementation of the change.

The FDA may require testing and surveillance programs to monitor the effect of products that have been commercialized, and has the power to prevent or limit further marketing of these products based on the results of these post-marketing programs. Product approvals may be contingent on an agreement to conduct specified post-marketing programs, and product approvals may be withdrawn after the product reaches the market if compliance with regulatory standards is not maintained or if problems occur regarding the safety or efficacy of the product. As the FDA s approval process comes under greater scrutiny by the government and the public, especially with regard to safety issues, we expect that

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the scope and frequency of post-marketing programs required as a condition of approval will increase. For example, the approval letter for Daytrana® requires post-marketing surveillance and post-marketing studies relating to the possibility of skin sensitization.

The approval procedures for the marketing of our products in foreign countries vary from country to country, and the time required for approval may be longer or shorter than that required for FDA approval. Even after foreign approvals are obtained, further delays may be encountered before products may be marketed. For example, many countries require additional governmental approval for price reimbursement under national health insurance systems or additional studies involving patients located in their countries.

Manufacturing facilities are subject to periodic inspections for compliance with the FDA s good manufacturing practices regulations and each domestic drug manufacturing facility must be registered with the FDA. Most foreign regulatory authorities have similar regulations. In complying with standards set forth in these regulations, we must expend significant time, money and effort in the area of quality assurance to ensure full technical compliance. Facilities handling controlled substances, such as ours, also must be licensed by the DEA, and are subject to more extensive regulatory requirements than those facilities not licensed to handle controlled substances. We also require approval of the DEA to obtain and possess controlled substances, including methylphenidate and amphetamine. We produce transdermal drug delivery products, and our third party manufacturers produce Stavzor®, Pexeva® and Lithobid®, in accordance with United States and international regulations for clinical trials, manufacturing process validation studies and commercial sale. FDA approval to manufacture a drug product is site specific. In the event our or any of our third party manufacturer s approved manufacturing facilities becomes inoperable, obtaining the required FDA approval to manufacture the applicable product at a different manufacturing site could result in production delays, which could adversely affect our business and results of operations.

Our activities are subject to various federal, state and local laws and regulations regarding occupational safety, sales practices, laboratory and manufacturing practices, environmental protection and hazardous substance control, and may be subject to other present and possible future local, state, federal and foreign regulations. Under certain of these laws, we could be liable for substantial costs and penalties in the event that waste is disposed of improperly. While it is impossible to accurately predict the future costs associated with environmental compliance and potential remediation activities, compliance with environmental laws is not expected to require significant future capital expenditures and has not had, and is not presently expected to have, a material adverse effect on our earnings or competitive position.

In addition, in recent years, several states and localities have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Many of these requirements are new and uncertain, and the penalties for failing to comply with these regulations are unclear. Furthermore, individual states, acting through their attorneys general, have become active, seeking to regulate the marketing of prescription drugs under state consumer protection and false advertising laws. We have a compliance program designed to monitor and assist us in our compliance with these rules and regulations.

Failure to comply with governmental regulations may result in fines, warning letters, unanticipated compliance expenditures, interruptions or suspension of production and resulting loss of sales, product seizures or recalls, injunctions prohibiting further sales,

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withdrawal of previously approved marketing applications and criminal prosecution. As discussed above under ADHD Therapy Daytrana®, we received a warning letter from the FDA in January 2008 and two Form 483 s primarily related to Daytrana®.

Backlog

Our backlog for Noven Transdermals totaled $0.4 million as of March 2, 2009, substantially all of which is expected to be filled during 2009. Our backlog for Noven Transdermals totaled $2.9 million as of March 7, 2008, all of which was filled during 2008. We did not have a backlog for Noven Therapeutics in 2008 or 2007.

Employees

As of March 2, 2009, we had approximately 610 employees, approximately 261 of which were engaged in manufacturing, process development, quality assurance and quality control, 223 in marketing and sales, 81 in general administration, 31 in research and development and 14 in clinical research and regulatory affairs. Included in these numbers are 85 individuals who became employees of Noven as a result of the Noven Therapeutics acquisition in August 2007. Also included are approximately 148 employees whose salaries are reimbursed, in whole or in part, by our Novogyne joint venture. No employee is represented by a union and we have never experienced a labor-related work stoppage. We believe our employee relations are good.

Seasonality

Although our business is affected by the purchasing patterns of our partners and wholesale drug distributors, there are no significant seasonal aspects to our existing business.

Available Information

Our website address is www.noven.com. Our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports are available free of charge through our website, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission (SEC). We also make available on our website the beneficial ownership reports (Forms 3, 4 and 5) filed by our officers, directors and other reporting persons under Section 16 of the Securities Exchange Act of 1934. Our website and the information contained therein or connected thereto are not incorporated into this annual report on Form 10-K.

Item 1A. Risk Factors.

This section summarizes certain risk factors that could adversely affect us or that may cause our results to differ materially from the forward-looking statements contained in this report or otherwise made by or on our behalf. The risks and uncertainties described below are not necessarily listed in order of probability or priority and are not the only ones we face. If any of the following risks actually occurs, our business, financial condition and results of operations could suffer. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business, financial condition and results of operations.

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Our business may be significantly harmed if we are unable to adequately resolve the issues raised by the FDA in the warning letter we received in January 2008.

In January 2008, we received a warning letter from the FDA in connection with the FDA s July 2007 inspection of our manufacturing facilities. In the warning letter, which is posted on the FDA s website, the FDA cited Current Good Manufacturing Practice deficiencies related to: (i) peel force specifications for removal of Daytrana ® s release liner; and (ii) data supporting the peel force characteristics of Daytrana ® s enhanced release liner throughout the product s shelf life. We submitted our response to the warning letter on January 30, 2008.

In January 2009, we received from the FDA a list of observations on Form 483 following an on-site inspection of our manufacturing facilities. Like the warning letter and the prior Form 483, the majority of the observations in the Form 483 relate to the manufacture of Daytrana® product that exhibits high peel force characteristics, an issue which Noven and Shire continue to work to resolve.

Unless the violations identified in the warning letter are corrected, the FDA may withhold approval of marketing applications relating to products manufactured at our Miami, Florida facility. Failure to adequately address the issues raised by the FDA in the warning letter as well as the production and other issues involving Daytrana® could result in additional regulatory action, including fines, recalls of products, injunctions, seizures, suspension of production or withdrawal of the approval of products. Any enforcement action would be expected to have a material adverse effect on us, including the potential for litigation related to this matter, harm to our reputation and various costs associated with the foregoing.

Recalls or withdrawals of our products could have a material adverse effect on our results of operations and financial condition.

Product recalls or withdrawals may be initiated at the discretion of Noven (if we have regulatory authority for the product), our partners (if they have regulatory authority for the product, as is the case for our Vivelle-Dot®, CombiPatch® and Daytrana® products), the FDA, other government agencies, or a combination of these parties. Our products may be recalled or we or our partners may withdraw products from the market for various reasons including the failure of our products to maintain their stability through their expiration dates, manufacturing issues, quality claims, safety issues or disputed labeling claims. As a general matter, manufacturing transdermal delivery systems is more complex than for oral products, which may increase the risk of a recall or market withdrawal of one or more of our transdermal products.

We have experienced a number of production issues, some of which have led to recalls and market withdrawals. In the third quarter of 2007, Shire initiated two voluntary recalls of a portion of the Daytrana® product on the market primarily in response to feedback from patients and caregivers who experienced difficulty removing the release liner from certain Daytrana® patches. We paid Shire $3.3 million in February 2008 related to the 2007 recalls. These costs were charged to operations in 2007. In 2008, we recorded additional expenses of

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approximately $3.7 million related to two additional voluntary recalls by Shire in 2008 of four lots of Daytrana® and certain previously-manufactured lots that would not have met the newly implemented release testing standard and are probable of being voluntarily withdrawn or recalled from the market prior to the expiration of their shelf life. In addition, during 2008, we established a reserve of $3.8 million related to these affected lots. We do expect that there will be an additional voluntary withdrawal/recall of some Daytrana® lots due to the peel force issue. While we believe the $3.8 million reserve is adequate for the costs of such withdrawal/recall, we cannot assure that our costs related to this issue will not exceed the amount reserved.

We do not carry insurance to cover the risk of a potential product recall or market withdrawal. A significant product recall or market withdrawal could materially affect our sales, the prescription trends for the products and our reputation and the reputation of the product. In these cases, our business, results of operations and financial condition could be materially and adversely affected.

Our approved products may not achieve the expected level of market acceptance.

Our success depends on the market acceptance of our products. Substantially all of our revenues have historically been generated through sales of transdermal delivery systems, which generally are more expensive than oral formulations. Our transdermal products are marketed primarily to physicians, some of whom are reluctant to prescribe a transdermal delivery system when an alternative delivery system is available. We and our licensees must demonstrate to prescribing physicians the benefits of transdermal delivery. The commercial success of our products is also based in part on patient preference, and difficulties in obtaining patient acceptance of our transdermal delivery systems may similarly impact our ability to market our transdermal products.

The market for Daytrana® has been and may continue to be negatively affected by the peel force issues, the FDA warning letter, Shire s 2007 and 2008 voluntary market recalls and other factors, although we have taken steps to implement enhancements to the Daytrana® release liner intended to improve ease of use of the patch. Our results of operations and financial condition could be adversely affected if the enhancements do not result in improved ease of use of the Daytrana® product throughout its shelf life.

If we cannot develop, license or acquire new products and commercialize them on a timely basis, including Mesafem, our financial condition and results of operations could be adversely affected.

Our long-term strategy is dependent upon the successful development and commercialization of new products. We cannot assure that we will be able to identify commercially promising products or technologies or additional indications to which our products and technologies may be beneficially applied. The length of time necessary to complete clinical trials and obtain marketing approval from regulatory authorities is considerable. We cannot assure that we will have the financial resources necessary to complete products under development, that those projects to which we dedicate resources will be successfully completed, that we will be able to obtain regulatory approval for any such product, or that any approved product can be produced in commercial quantities, at reasonable costs, and be successfully marketed, either by us or by a licensing partner. A project can fail or be delayed at any stage of development, even if each prior stage was completed successfully, which could jeopardize our ability to recover our investment in the product. Some of our development projects will not be completed successfully or on schedule. Many of the factors that may cause a product in development to fail or be delayed are beyond our control. Mesafem, our

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women s health product under development for the treatment of vasomotor symptoms associated with menopause, is in Phase 2 clinical trials. We cannot assure that Phase 2 clinical trials for Mesafem will be successful, and even if they are successful, whether Phase 3 clinical trials will ultimately be successful.

Furthermore, the potential success of a new pharmaceutical product is subject to many risks which could have a material adverse effect on our business, financial condition and results of operations, including, but not limited to: (i) the failure of ongoing and planned clinical trials and the risk that results from early-stage clinical trials may not be indicative of results in later-stage trials; (ii) the unproven safety and efficacy of products under development; (iii) the difficulty of predicting FDA approval, including the timing of approval and that approval may not be granted at all; (iv) while FDA approval may be granted, the possibility that any expected period of exclusivity may not be realized and that we may not be able to produce commercially viable quantities; (v) the impact of competitive products, pricing and managed care and formulary status; (vi) the possibility that any product launch may be delayed or that product acceptance and demand may be less than anticipated; (vii) the possibility that patent applications may not result in issued patents and that issued patents may not be enforceable or could be invalidated; (viii) the commercial markets that we intend to enter with new products may not develop in the manner or to the extent that we anticipate; and (ix) the potential negative impact of competitive responses to our sales, marketing and strategic efforts.

From time to time, we may need to acquire licenses to patents and other intellectual property of third parties to develop, manufacture and commercialize our products. We cannot assure that we will be able to acquire such licenses on commercially reasonable terms or at all. The failure to obtain such a license could negatively affect our ability to develop, manufacture and commercialize certain products. In some cases, we have begun and, in the future, may begin developing a product with the expectation that a licensee will be identified to assist in completing development and/or marketing. We cannot assure that we will attract a business partner for any particular product or will be able to negotiate an agreement on commercially reasonable terms. If an agreement is not reached, our initial development investment in any such product may not be recovered.

In order to diversify and complement our current product offerings, we may pursue new product and technology acquisitions, which may be costly and may not provide the expected benefits.

One of our current growth strategies is to diversify our transdermal product offerings (beyond ADHD and HT) and complement our therapeutic product offerings through, among other things, new product acquisitions or the license or purchase of rights to new technologies. If we undertake any such product or technology acquisition, the process of integrating the new product or technology may result in unforeseen operating difficulties and expenditures and may divert significant management attention from our ongoing business operations. We may fail to realize the anticipated benefits of any such acquisition for a variety of reasons, including as a result of an acquired technology proving to not be safe or effective in later clinical trials, the technology being found to infringe upon the intellectual property rights of a third party or the acquired product or technology achieving less market acceptance or commercial success than anticipated. We may fund any future acquisition through debt financing or the issuance of equity or debt securities, which could dilute the ownership percentage of current stockholders or limit our financial or operating flexibility as a result of restrictive covenants related to new debt. Such funds may not be available on terms that are favorable to us, or at all due to current economic conditions and extremely tight credit markets. Acquisition efforts, whether consummated or not, can consume significant management attention and require substantial expenditures, which could detract from our other programs.

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We may be unable to obtain marketing approval for our new products on a timely basis or at all.

We are not able to market our products in the United States or other jurisdictions without first obtaining marketing approval from the FDA or an equivalent foreign agency. The process of obtaining FDA approval for a new product is risky, expensive and may take several years. The process is subject to the broad authority and discretion of the FDA.

We cannot assure that we will obtain the necessary regulatory approval for our products under development when expected, or at all, or that any such approval will be free from unduly burdensome conditions or limitations. In light of the WHI and other HT studies, as well as publicity surrounding COX-2 inhibitors and certain antidepressants, it is possible that healthcare regulators, including the FDA and the Drug Safety Oversight Board, could delay the approval of certain products or require that any such new products be subject to more extensive or more rigorous study and testing prior to being approved or be subject to more extensive conditions, limitations or monitoring after approval. We cannot predict what effect future changes in regulations or legal interpretations, if, when and as ultimately promulgated, may have on our business.

We may not realize the expected benefits of the Noven Therapeutics acquisition.

We may be unable to take advantage of the opportunities that we expect to obtain from the Noven Therapeutics acquisition. We cannot assure the future commercial success of the currently marketed products or that Mesafem, an important developmental product acquired in the acquisition, will receive marketing approval or achieve commercial success. The potential success of any new pharmaceutical product is subject to a number of risks and uncertainties, including, among others, the risks and uncertainties described in the preceding risk factors.

The Noven Therapeutics acquisition is expected to dilute our earnings for an undetermined period of time.

Our financial results reflect significant amortization and other ongoing integration-related expenses associated with our acquisition of Noven Therapeutics. In addition, we plan to increase our research and development expenses significantly over the next several years as we advance the development of Mesafem. We cannot assure the future success of this product or whether we will be able to recover our initial and ongoing investment in Noven Therapeutics and its products.

Publication of negative results of studies or clinical trials may adversely impact our products.

From time to time, studies or clinical trials on various aspects of pharmaceutical products are conducted by academics or others, including government agencies, the results of which, when published, may have dramatic effects on the markets for the pharmaceutical products that are the subject of the study and on other similar or related pharmaceutical products. The publication of negative results of studies or clinical trials related to our products or the areas in which our products compete could adversely affect our sales, the prescription trends for our products and the reputation of our products and could also cause us to be a target for product liability or other lawsuits.

Currently, our liquidity, results of operations and business prospects are significantly dependent on sales, license royalties and fees associated with transdermal HT products and to a lesser extent, Daytrana®. The market for HT products has been negatively affected by the WHI study and other studies that have found that the overall health risks from the use of certain HT products exceed the benefits from the use

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of those products among healthy postmenopausal women. For example, total prescriptions dispensed in the HT market in the United States declined by 56% from 2002 (the year of publication of the results of the WHI study) to 2008. In addition, a private foundation has commenced a five-year study aimed at determining whether ET use by women aged 42 to 58 reduces the risks of heart disease. The study also seeks to determine if transdermal estrogen patches are more or less beneficial than an oral HT product. The market for HT products, including ours, both in the United States and abroad, could be further adversely impacted if this or other HT studies find unacceptable risks from the use of HT products. Any further adverse change in the market for HT products could have a material adverse impact on our business, financial condition and results of operations.

The FDA s analysis of potential safety issues associated with certain transdermal products, including Duragesic® and Ortho Evra®, and the resulting media coverage of these issues, may adversely affect the public s and the medical community s perceptions of other transdermal products, including our transdermal products, and could ultimately impair the commercial acceptance of our current and future transdermal products.

We do not control Novogyne, and we may face additional risks because Novartis, our joint venture partner, has significantly greater resources than we have.

Our profitability has been dependent on our equity in Novogyne s earnings, and Novogyne s results will likely continue to be material to us in the future. Because, among other things, we are much smaller than Novartis, and because Novartis and its affiliates sell competing products outside of Novogyne, our interests may not always be aligned. This may result in potential conflicts between Novartis and us on matters relating to Novogyne that we may not be able to resolve on favorable terms or at all. Under the Novogyne joint venture agreement, Novartis has the right to dissolve Novogyne under certain circumstances. Novogyne s Management Committee is comprised of a majority of representatives from Novartis. While certain significant corporate actions require the supermajority vote of the Management Committee members, we do not control Novogyne. In addition, the joint venture operating agreement has a buy/sell provision that either Noven or Novartis may trigger by notifying the other party of the price at which the triggering party would be willing to acquire the other party s entire interest in the joint venture. Novartis is a larger company with greater financial resources than we have and, therefore, may be in a better position to be the purchaser if the provision is triggered. If the buy/sell provision is triggered and Novartis is the purchaser, we cannot assure that we would be able to reinvest the proceeds of the sale in a manner that would result in sufficient earnings to offset the loss of earnings from Novogyne. If the provision is triggered and we are the purchaser, we cannot assure that we would be able to adequately perform the services currently being provided by Novartis or that we would not be adversely affected by the changes in capital and/or debt structure that would likely be required to finance the purchase.

We depend on Novartis to perform financial, accounting, regulatory, compliance, inventory, sales deductions and other functions for Novogyne.

Under the Novogyne joint venture agreements, Novartis is responsible for providing Novogyne with all financial, accounting, legal and regulatory services, including monitoring inventory levels and estimating and recording sales allowances and returns for Novogyne (which include reserves and allowances related to product returns), and is primarily responsible for ensuring compliance with applicable regulations relating to sales and marketing activities. Novartis is also responsible for the establishment and maintenance of internal controls for Novogyne. As a result, our ability to assess their effectiveness at maintaining those internal controls is necessarily limited. Failure by Novartis to perform its obligations under the joint venture agreements could negatively affect the financial condition and results of operations of Novogyne and

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Noven. Further, any material errors in Novogyne s financial statements could lead to a restatement of Novogyne s financial statements, which would likely require us to restate our financial statements.

We depend on partners to obtain regulatory approval for, and to market and sell, certain of our transdermal products. Our marketing partners sell products that compete with our transdermal products.

We depend upon collaborative agreements with other pharmaceutical companies to obtain regulatory approval for and to market and sell certain of our transdermal products. To help alleviate the up-front financial burden of seeking product approval and commercializing products, we often seek out strategic partners to whom we can license our transdermal products. Under the terms of the Novogyne joint venture, Novartis is responsible for the distribution of Novogyne s products, including Vivelle-Dot®, and for selling Novogyne s products to its trade customers. For Daytrana®, we have granted the exclusive marketing rights to Shire. Failure of Novartis, Shire or our other partners to adequately support our transdermal products would cause the quantity of products purchased from us and the amount of fees and royalties ultimately paid to us to be reduced and would therefore have a material adverse effect on our business and operations. Our partners may have different and, sometimes, competing priorities from ours. Some of our partners, including Novartis and Shire, market and sell transdermal products competitive with our transdermal products. Shire has a portfolio of ADHD products and, in February 2007, received marketing approval for Vyvanse®, an amphetamine pro drug for the treatment of ADHD which competes with our Daytrana® product. Shire dedicated substantial resources to the promotion of this product. The marketing organizations of our partners may be unsuccessful, or those partners may assign a lower level of priority to the marketing of our transdermal products. Our agreements with Shire required Shire to use commercial efforts to market Daytrana® until payment of all milestone payments, but Shire has no obligation to continue marketing Daytrana® thereafter. We have already received all such milestone payments. If one or more partners fails to pursue the marketing of our transdermal products as planned, or if marketing of any of those products is otherwise delayed, our business, financial condition and results of operations may be negatively affected. Absent these marketing partners, we do not presently have a significant direct marketing channel to health care providers for our transdermal products.

Failure to comply with our supply agreements or otherwise adequately supply our transdermal products to our licensees could negatively affect our financial condition and results of operations.

Our supply agreements with our licensees for our transdermal products impose strict obligations on us with respect to the manufacturing and supply of our transdermal products. Failure to comply with the terms of these supply agreements may result in our being unable to supply our transdermal products to our licensees, resulting in lost revenues by us and potential responsibility for damages and losses suffered by our licensees. Our supply agreement with Novogyne for Vivelle-Dot® has expired. Since the expiration of that supply agreement, the parties have continued to operate in accordance with certain of the supply agreement s pricing terms. We cannot assure that we and Novogyne will continue to operate under the supply agreement in accordance with certain of its pricing terms or that we will enter into a new supply agreement on satisfactory terms or at all. Due to our dependence on Novogyne, we may be unable to negotiate favorable business terms with them or resolve any dispute that we may be involved in with them in a favorable manner. Failure to continue operating in accordance with certain of the supply agreement s pricing terms could have a material adverse effect on our business, results of operations and financial condition. Designation of a new supplier and approval of a new supply agreement would require the affirmative vote of four of the five members of Novogyne s Management Committee. Accordingly, both Novartis and Noven must agree on Novogyne s supplier.

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We face scale-up risks in manufacturing new transdermal products in commercial quantities.

Inefficiencies and other scale-up problems can occur in the process of manufacturing new products in commercial quantities. If we do not adequately and timely scale-up our manufacturing processes for new transdermal products or otherwise meet supply requirements for these transdermal products, the success of our new transdermal product launches, revenues and product gross margins could be adversely affected. Significant scale-up or other manufacturing problems could also cause our collaboration partners, if permitted under our agreements, to rely more heavily on second manufacturing sources, thus reducing the manufacturing revenues that we would otherwise realize. It could also jeopardize our ability to obtain milestone payments. If we experience manufacturing difficulties such as quality problems, yield deficiencies or similar issues, our overall manufacturing costs may be higher than anticipated.

We rely on third party manufacturers to supply us with our oral products. Failure of these third parties to comply with governmental regulations or our manufacturing and supply agreements or otherwise supply our oral products could negatively affect our financial condition and results of operations.

We rely upon third party manufacturers to manufacture and supply us with Stavzor®, Pexeva®, and Lithobid®, which are marketed and sold by Noven Therapeutics. We depend on these third party manufacturers to perform their obligations in a timely manner and in accordance with applicable governmental regulations and their agreements with us, and any production issues experienced by these third party manufacturers or delays in shipping products to us may affect our product supply and ultimately have a negative impact on our sales and profitability.

All manufacturers of pharmaceutical products sold in the United States must comply with the FDA s good manufacturing practices, and manufacturing operations and processes are subject to FDA inspection. Failure to comply with FDA or other governmental regulations can lead to the shutdown of a manufacturing facility, the seizure of a product distributed by that facility and other sanctions. Furthermore, changes in the manufacturing process or procedure, including a change in the location where the product is manufactured or a change of a third party manufacturer, may require prior review and approval in accordance with the FDA s good manufacturing practices. This review may be costly and time-consuming and could delay or prevent the launch of a product. The FDA at any time may also implement new standards, or change their interpretation and enforcement of existing standards for manufacture of products, and if the third party manufacturers are unable to comply, they may be subject to regulatory action, civil actions or other sanctions.

In addition, our third party manufacturers may encounter difficulties, including, but not limited to the following: (i) inconsistent production yields and difficulties in scaling production to commercial and validation sizes; (ii) difficulties obtaining raw materials; (iii) equipment failures, potential facility catastrophes and plant time scheduling issues; (iv) quality control and assurance issues; and (v) lack of regulatory compliance with the FDA s, or other agencies , regulations and specifications.

Furthermore, we have no control over whether the third party manufacturers breach their agreements with us or whether they terminate or decline to renew agreements with us. Defective products or other problems caused by our third party manufacturers could expose us to liability to others for which we may not have adequate recourse against our third party manufacturers. If there is poor manufacturing performance on the part of our third party manufacturers or we are contractually prohibited or unable to enter into agreements with additional

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manufacturers, if necessary, on commercially reasonable terms, we may not be able to meet commercial demand for Noven Therapeutics products or complete the development of, or successfully market, our products under development. Any of the above factors could interrupt our ability to sell our products and adversely affect our present and future sales margins, market share and product pipeline, as well as harm our overall business.

We rely on a single supplier or a limited number of suppliers for certain raw materials and compounds used in our transdermal products.

Certain raw materials and components used in manufacturing our transdermal products, including essential polymer adhesives, are available from limited sources, and, in some cases, a single source. Without adequate approved supplies of raw materials or packaging supplies, our manufacturing operations relating to our transdermal products could be interrupted until another supplier is identified, our transdermal products approved and trading terms with this new supplier negotiated. We may not be able to identify an alternative supplier and any supplier that we do identify may not be able to obtain the requisite regulatory approvals in a timely manner or at all. Furthermore, we may not be able to negotiate favorable terms with an alternative supplier. Any disruptions in our manufacturing operations from the loss of an approved supplier may cause us to incur increased costs and lose revenues and may have an adverse effect on our relationships with our partners and customers, any of which could have adverse effects on our business and results of operations. Some raw materials used in our transdermal products are supplied by companies that restrict certain medical uses of their products. While our use is presently acceptable, we cannot assure that such companies will not expand their restrictions to include our applications. Our business also faces the risk that third party suppliers may supply us with raw materials that do not meet required specifications, which, if undetected by us, could cause our transdermal products to test out of specification and require us to recall the affected product.

Our supply of methylphenidate and other controlled substances must be approved by the DEA.

Regulatory authorities must generally approve raw material sources for transdermal products and, in the case of controlled substances, the DEA sets quotas for controlled substances, including methylphenidate and amphetamine, and we must receive authorization from the DEA to handle these substances. Similarly, the manufacturers who supply the controlled substances to us must also receive authorization from the DEA to manufacture the substances. We cannot assure that we or our suppliers will be granted sufficient DEA quota to meet our production requirements for controlled substances. Previous grants of methylphenidate quota for Daytrana® have been less than originally requested, and we have had to re-apply for additional quota. We expect that this application and re-application process will continue with respect to future grants. We cannot guarantee that the timing or quantity of future DEA awards of methylphenidate quota will be sufficient for us to meet our production requirements for Daytrana®, and the timing and quantity of any future award may impact our production costs and market penetration of Daytrana®.

Compliance with governmental regulation is critical to our business.

Our operations are subject to extensive regulation by governmental authorities in the United States and other countries with respect to the development, testing, approval, manufacturing, labeling, marketing and sale of pharmaceutical products. These regulations are wide-ranging and govern, among other things: adverse drug experience reporting; product promotion; product pricing and discounting; drug sample accountability; drug product stability; product manufacturing, including good manufacturing practices; and product changes or modifications.

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In addition, our Miami manufacturing facilities handle controlled substances, resulting in additional extensive regulatory requirements and oversight. Compliance with the extensive government regulations applicable to our business requires the allocation of significant time, effort and expense. Even if a product is approved by a regulatory authority, product approvals may be withdrawn after the product reaches the market if compliance with regulatory standards is not maintained or if problems occur regarding the safety or efficacy of the product. Failure to comply with governmental regulations may result in fines, warning letters or other negative written observations, unanticipated compliance expenditures, interruptions or suspension of production and resulting loss of sales, product seizures or recalls, injunctions prohibiting further sales, withdrawal of previously approved marketing applications and criminal prosecution. Under the terms of the Novogyne joint venture, Novartis is responsible for providing regulatory services. We cannot assure that Novartis will comply with these regulations or that any violation by Novartis will not have an adverse effect on us.

In addition, in recent years, several states and localities have either enacted, or are considering enacting, legislation requiring pharmaceutical companies to establish marketing compliance programs, and file periodic reports with the state or make periodic public disclosures on sales, marketing, pricing, clinical trials, and other activities. Many of these requirements are new and uncertain, and the penalties for failing to comply with these regulations are unclear. Furthermore, individual states, acting through their attorneys general, have become active, seeking to regulate the marketing of prescription drugs under state consumer protection and false advertising laws. As a result of the Noven Therapeutics acquisition, we market and sell our therapeutic products through our own sales force. We have recently implemented a compliance program designed to monitor and assist us in our compliance with these rules and regulations. If we are not in full compliance with these laws, we could face enforcement action and fines and other penalties, and could receive adverse publicity.

If we market products in a manner that violates health care fraud and abuse laws, we may be subject to civil or criminal penalties.

Federal health care program anti-kickback statutes prohibit, among other things, knowingly and willfully soliciting or receiving any remuneration in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering, any good, facility or service that is reimbursable under Medicare, Medicaid or other federally financed health care programs. These statutes have been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, patients, purchasers and formulary managers, on the other. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending any good, facility, or service which is reimbursable under Medicare, Medicaid or other federally financed health care program may be subject to scrutiny if such practices do not qualify for an exemption or safe harbor.

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. Pharmaceutical companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as allegedly providing free products to customers with the expectation that the customers would bill federal programs for such products, reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates, engaging in promotion for uses that the FDA has not

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approved, or off-label uses, that caused claims to be submitted to Medicaid for non-covered off-label uses and submitting inflated best price information to the Medicaid Rebate Program.

The majority of states also have statutes or regulations similar to the federal anti-kickback statutes and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer s products from reimbursement under government programs, criminal fines and imprisonment. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which would have an adverse impact on our financial condition. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws.

Decreased margins on sales of Daytrana® may adversely impact our results of operations.

The price at which we sell Daytrana® to Shire is generally fixed and is determined in accordance with the terms of our supply agreement with Shire. Consequently, our margin on sales of Daytrana® is determined by our production costs and yields. If our production yields decrease or our costs of production for Daytrana® increase, our profitability will be adversely impacted. In particular, we have incurred and expect to incur in 2009 increased quality assurance costs related to the Daytrana® peel force issue and our efforts to address the concerns raised by the FDA in the two Form 483 s and the warning letter. Our ability to produce Daytrana® and continue to improve the gross sales margin is contingent on, among other things, resolving the peel force issue and receiving a sufficient supply of the active methylphenidate ingredient from Shire, as well as sufficient quota of the controlled substance from the DEA. At any given time, we expect to have applications pending with the DEA for annual or additional procurement quota that may be critical to continued production. Any delay or stoppage in the supply of the active methylphenidate ingredient could cause us to lose revenues or incur additional costs (including those related to expedited production), which could have an adverse effect on our results of operations.

We face significant competition, which may result in others discovering, developing or commercializing products before, or more successfully than, we do.

We face competition from a number of companies in the development of our products, and competition is expected to intensify as more companies enter the markets in which we operate. Some of these companies are substantially larger than we are and have greater resources and greater experience in developing and commercializing pharmaceutical products than we have. As a result, they may succeed before us in developing competing technologies or obtaining regulatory approvals for products.

Our transdermal products compete with other transdermal products, alternative dosage forms of the same or comparable chemical entities and non-drug therapies. We face competition in the HT market as new and innovative products continue to be introduced in this field, including products using alternative delivery systems such as sprays, lower-dosage products and products that may be used to treat menopause-related symptoms that are not hormone-based or that may reduce the risks related to hormone-based products. We may also face competition for our Vivelle-Dot® product from generic equivalents, which could erode market demand for the product, exerting pricing pressure on our product and consequently adversely impact our results of operations and financial condition. The ADHD market is highly competitive, and our

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competitors include our partner Shire, which markets other ADHD products, including Vyvanse®, an amphetamine pro drug for the treatment of ADHD. Other competitors marketing or developing ADHD products include Johnson & Johnson, Novartis, GlaxoSmithKline, Bristol-Myers Squibb, Abbott Laboratories, Celltech, and Lilly.

We cannot assure that our transdermal products and technologies will remain competitive. If we cannot maintain competitive transdermal products and technologies, our current and potential strategic partners may choose to adopt the drug delivery technologies of our competitors or their own internally developed technologies, which could adversely impact our results of operations and financial condition.

Our oral products also participate in highly competitive markets. In the SSRI market and the market for the treatment of bipolar disorder, we compete against, among others, Lilly, GlaxoSmithKline, AstraZeneca and Pfizer, each of which is substantially larger and has greater financial resources than we have. Stavzor® competes against, among others, Abbott Laboratories Depakote® product and its generic equivalents. In addition, Pexeva® faces competition in the SSRI market from generic versions of similar products and Lithobid® competes against generic versions of lithium products, including an AB-rated generic to Lithobid®. Manufacturers of generic products typically do not bear significant research and development or education and marketing development costs and consequently may be able to offer their products at considerably lower prices than we can offer our products.

We cannot assure that our products will compete successfully against competitive products or that developments by others will not render our products obsolete or uncompetitive. If we cannot maintain competitive products, our results of operations and financial condition would be adversely impacted.

Competitors may use legal, regulatory and legislative strategies to prevent or delay the launch of our products.

Competitors may pursue legislative and other regulatory or litigation strategies to prevent or delay the launch of our products. These strategies include, but are not limited to: seeking to obtain new patents on drugs for which patent protection is near expiration; changing the labeling for the branded product; filing a citizen s petition with the FDA; pursuing state legislative efforts to limit the substitution of generic versions of branded pharmaceuticals; filing patent infringement lawsuits that automatically delay FDA approval of many generic products; introducing a second generation product prior to the expiration of market exclusivity for the first generation product, which may reduce demand for a generic first generation product; and obtaining market exclusivity extensions by conducting pediatric trials of brand drugs.

The Hatch-Waxman Act provides for a generic marketing exclusivity period of 180 days for each ANDA applicant that is first to file an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed in the FDA Orange Book with respect to a reference listed drug product, commonly referred to as a Paragraph IV certification. During this exclusivity period, the FDA cannot grant final approval to any other Paragraph IV filer. If an ANDA containing a Paragraph IV certification is successful, it generally results in higher market share, net revenues and gross margin for that applicant for a period of time. Even if we obtain FDA approval for generic drug products, we may have a significant disadvantage against a competitor who was first to file an ANDA containing a Paragraph IV certification.

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The European market for our transdermal products may be limited due to pricing pressures and other matters.

Pharmaceutical prices, including prices for our transdermal products, in Europe and certain other regions are significantly lower than in the United States. Because our agreements with Novartis Pharma provide for us to receive a percentage of Novartis Pharma s net selling price (subject to a minimum price), our gross margins are generally much lower for transdermal products sold to Novartis Pharma for resale outside of the United States than for the same products sold to Novogyne for sale in the United States. In addition, the lower prices restrict Novartis Pharma s gross margin realized from selling our transdermal products. Because our transdermal products compete for sales and marketing resources with other Novartis Pharma products, including competitive HT products, we cannot assure that the relatively low gross margins generated from selling our transdermal products will not cause Novartis Pharma to focus its resources on other products or even not launch our transdermal products in certain countries. Novartis Pharma has launched Estradot® in the United Kingdom, France, Germany and Spain (without the benefit of government reimbursement) and in a number of smaller European countries.

Our quarterly operating results are subject to significant fluctuations.

In 2008, we experienced significant fluctuations in our quarterly operating results and we expect that revenues from product sales and our research and development expenditures will continue to fluctuate from quarter-to-quarter and year-to-year depending upon various factors not in our control. These factors include, without limitation: the timing of FDA approval and subsequent timing and success of any new transdermal or therapeutic product launch; the purchasing patterns of wholesale drug distributors; marketing efforts of our licensees relating to our transdermal products; fluctuations in sales and returns allowances, including those related to allowances for expiring products as well as product recalls; the inventory requirements of each licensee for our transdermal products; the impact of competitive products; the impact of the HT studies on prescriptions for our HT products; the transdermal product pricing of each licensee; the timing of certain royalty reconciliations and payments under our license agreements for our transdermal products; and the success of Shire s sales and marketing efforts for Daytrana®. Our earnings may also fluctuate because of, among other things, fluctuations in research and development expenses resulting from the timing of clinical trials and our efforts to bring Mesafem to market. In addition, Novartis is entitled to an annual $6.1 million preferred return over our interest in Novogyne, which has had the effect of reducing our share of Novogyne s income in the first quarter of each year.

Our results of operations will be adversely affected if we or Novogyne fail to realize the full value of our intangible assets, which significantly increased as a result of the Noven Therapeutics acquisition.

Accounting principles generally accepted in the United States require us and Novogyne to test the recoverability of our respective long-lived assets and certain identifiable intangible assets whenever events or changes in circumstances indicate that those assets carrying amounts may not be recoverable. If the fair value is less than the carrying amount of the asset, a loss is recognized for the difference. Novogyne recorded the acquisition of the CombiPatch® product marketing rights at cost and tests this asset for impairment when factors indicate there may be a possible impairment. In addition, intangible assets in the form of patent development costs and goodwill from the acquisition of Noven Therapeutics comprise a significant portion of our total assets. Goodwill is tested for impairment annually in the fourth quarter or more frequently, when events or other changes in circumstances indicate that the carrying value of goodwill may not be recoverable. If after testing

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the intangible assets and goodwill, we (or Novogyne) determine that these assets are impaired, then we (or Novogyne) would be required to write-down the impaired asset to fair value in the period when the determination is made. Such a write-down could have a material adverse effect on our results of operations.

We previously invested a portion of our cash in auction rate securities, which subjects us to liquidity and investment risk. We could be required to record additional impairment charges if the fair value of these investments continues to decline.

At December 31, 2008, we held investments in auction rate securities (classified as available-for-sale) with a par value and fair value of $16.0 million and $15.5 million, respectively. Auction rate securities are floating rate debt securities with long-term nominal maturities, the interest rates of which are reset periodically (typically every seven to thirty-five days) through a Dutch auction process. Beginning in February 2008, as part of the ongoing credit market crisis, several auction rate securities from various issuers have failed to receive sufficient order interest from potential investors to clear successfully, resulting in auction failures. As a result of failed auctions, these investments now pay interest at a rate defined by the governing documents or indenture.

In 2008, we liquidated a substantial portion of our auction rate securities at par and recorded unrealized losses of $0.5 million to reduce the remaining investments to fair value, which impairments were determined to be other-than-temporary and recognized in our 2008 Consolidated Statement of Operations.

Our auction rate security investments are collateralized primarily by tax-exempt municipal bonds and, to a much lesser extent, guaranteed student loans. We do not hold any auction rate securities collateralized by mortgages or collateralized debt obligations. We believe our investments are of high credit quality, as all are investment grade and the majority are rated AA or higher. In assessing whether declines in fair value are temporary in nature or other-than-temporary, management considers a variety of factors, including our recent history of liquidating similar instruments at par value, the length of time and extent to which the fair value has been less than par, the financial condition of the issuer of the investment and management s intent and ability to retain the investments for a sufficient period to allow for any anticipated recovery in fair value. In the fourth quarter of 2008, management determined that the $0.5 million unrealized decline in fair value of our auction rate securities was other-than-temporary. We will continue to monitor the market for our auction rate security investments. If management determines in a future period that existing temporary declines or further declines in fair value are other-than-temporary, we will be required to record a charge to operations in the period when such determination is made. As illiquid conditions persist in the auction market for these securities, it may become increasingly more likely that we will need to recognize additional other-than-temporary impairment charges in future periods. Such non-cash impairment charges could materially and adversely affect our consolidated financial condition and results of operations. See Note 5 Investments Available-for-Sale , in the Notes to our Consolidated Financial Statements for further information.

There are inherent uncertainties involved in the estimates, judgments and assumptions used in the preparation of our consolidated financial statements, and any changes in those estimates, judgments and assumptions could have a material adverse effect on our financial condition and results of operations.

The consolidated and condensed consolidated financial statements that we file with the SEC are prepared in accordance with United States generally accepted accounting principles (GAAP). The preparation of financial statements in accordance with GAAP involves making

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estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities. The most significant estimates we are required to make under GAAP include, but are not limited to, those related to revenue recognition, sales allowances, inventories and cost of goods sold, determining the useful life or impairment of goodwill and other long-lived assets, litigation settlements and related liabilities, and income taxes. We periodically evaluate estimates used in the preparation of the consolidated financial statements for reasonableness, including estimates provided by third parties. Appropriate adjustments to the estimates will be made prospectively, as necessary, based on these periodic evaluations. We base our estimates on, among other things, currently available information, market conditions, historical experience and various assumptions, which together form the basis of judgments underlying the carrying values of assets and liabilities that are not readily apparent from other sources. Although we believe that our assumptions are reasonable under the circumstances, estimates would differ if different assumptions were utilized and these estimates may prove in the future to have been inaccurate.

If our estimates for returned products are incorrect, there could be a materially adverse impact on our net revenues and results of operations.

In the pharmaceutical industry, our customers are normally granted the right to return a product for a refund if the product has not been used by its expiration date or for a period of one year thereafter. Management is required to estimate the amount of product that will ultimately be returned pursuant to our return policy and to record a related reserve at the time of sale. These amounts are deducted from our gross revenues to determine our net revenues. We believe that we have sufficient data to estimate future returns at the time of sale of our products, except for Stavzor®, for which we do not yet have sufficient sales history to reasonably estimate returns. Management periodically reviews the allowances for returns and adjusts them based on actual experience. In order to reasonably estimate future returns, we analyze both quantitative and qualitative information including, but not limited to, actual return rates by product, the level of product in the distribution channel, expected shelf life of the product, product demand, the introduction of competitive or generic products that may erode current demand, our new product launches and general economic and industry wide indicators. There are inherent limitations in estimating future product returns due to the time lapse between sale and actual return of the product. If we over- or under-estimate the amount of product that will ultimately be returned, there could be a material impact to our results of operations.

We cannot be certain of the protection or confidentiality of our patents and proprietary rights.

Our success will depend, in part, on our ability to obtain or license patents for our products, processes and technologies. If we do not do so, our competitors may exploit our innovations and deprive us of the ability to realize revenues from those innovations. We cannot assure that we will be issued patents for any of our patent applications, that any existing or future patents that we receive or license will provide competitive advantages for our products, or that we will be able to enforce successfully our patent rights. Specifically, Pexeva® and Mesafem are subject to a composition of matter patent that extends to 2017. However, recent Supreme Court case law (unrelated to our patent) may make it easier to challenge the validity of this patent on grounds of obviousness. If we are unable to successfully enforce our patent rights, including our patent rights relating to Pexeva® and Mesafem, our results of operations and financial condition may be adversely impacted.

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Additionally, we cannot assure that our patents or any future patents will prevent third parties from developing similar or functionally equivalent products, or challenging, invalidating or avoiding our patent applications or any existing or future patents that we receive or license. The patents related to Vivelle-Dot® and other of our transdermal products are formulation patents and do not preclude others from developing and marketing products that deliver drugs transdermally or otherwise through non-infringing formulations. Furthermore, we cannot assure that any of our future processes or products will be patentable, that any pending or additional patents will be issued in any or all appropriate jurisdictions or that our processes or products will not infringe upon the patents of third parties.

We also rely on trade secrets, unpatented proprietary know-how and continuing technological innovation. We use confidentiality agreements with licensees, manufacturers, suppliers, employees and consultants to protect our trade secrets, unpatented proprietary know-how and continuing technological innovation, but we cannot assure that these parties will not breach their agreements with us or that we will be able to effectively enforce our rights under those agreements. We also cannot be certain that we will have adequate remedies for any breach. Disputes may arise concerning the ownership of intellectual property or the applicability of confidentiality agreements. Furthermore, we cannot be sure that our trade secrets and proprietary technology will not otherwise become known or that our competitors will not independently develop our trade secrets and proprietary technology.

Third parties may claim that we infringe their proprietary rights, forcing us to expend substantial resources in resulting litigation, the outcome of which is uncertain. Any unfavorable outcome could negatively affect our financial condition and results of operations.

Our success depends, in part, on our ability to operate without infringing the proprietary rights of others, and we cannot assure that our products and processes will not infringe upon the patents of others. Third parties may also institute patent litigation against us for competitive reasons unrelated to any infringement by us. If a third party asserts a claim of infringement, we may have to seek licenses, defend infringement actions or challenge the validity of those third-party patents in court. If we cannot obtain the required licenses, or are found liable for infringement or are not able to have these patents declared invalid, we may be liable for significant monetary damages, encounter significant delays in bringing products to market or be precluded from participating in the manufacture, use or sale of products or methods of drug delivery covered by the patents of others. We cannot assure that we have identified, or that in the future we will be able to identify, all United States and foreign patents that may pose a risk of potential infringement claims.

In June 2007, Johnson-Matthey Inc. filed a complaint in the United States District Court, Eastern District of Texas, against us alleging that we were infringing one of its patents through our manufacturing and sale of Daytrana®. The plaintiff is seeking injunctions from further infringement and claiming compensatory and other damages in an unspecified amount. In July 2007, Johnson-Matthey added Shire as a defendant in this lawsuit. The parties have commenced formal discovery and the case has been scheduled for trial in late 2009. We intend to vigorously defend this lawsuit, but the outcome cannot ultimately be predicted. See Note 19 Commitments and Contingencies Litigation, Claims and Assessments, in the Notes to our Consolidated Financial Statements.

We may experience reductions in the levels of reimbursement for our products by governmental authorities, private health insurers and managed care organizations.

Our ability and our marketing partners ability to successfully commercialize our products is dependent in part on obtaining reimbursement from government health authorities, private health insurers and managed care organizations. The trend toward managed

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healthcare in the United States and the prominence of health maintenance organizations (HMOs) and similar entities could significantly influence the purchase of our products, resulting in lower prices and lower demand. This is particularly true in a market that includes generic alternatives, such as the ADHD and SSRI markets, as well as the market for the treatment of bipolar disorder. In addition, managed care agreements established by Novartis could adversely affect Novogyne s financial results.

We are subject to chargebacks and rebates when our products are resold to, or reimbursed by, governmental agencies and managed care buying groups, which may reduce our net revenues and impact our results of operations.

Chargebacks and rebates are the difference between the prices at which we sell our products to wholesalers and the price that third party payors, such as governmental agencies and managed care buying groups, ultimately pay pursuant to pre-determined contract prices and discounts. Medicare, Medicaid and reimbursement legislation or programs regulate drug coverage and reimbursement levels for most of the population in the United States. Federal law requires all pharmaceutical manufacturers who participate in the Medicaid program to rebate a percentage of their revenue arising from Medicaid-reimbursed drug sales to individual states. We record an estimate of the amount either to be charged back to us or rebated to the end-users at the time of sale to the wholesaler. Managed care organizations use these chargebacks and rebates as a method to reduce overall costs in drug procurement. We record an accrual for chargebacks and rebates based upon factors including current contract prices, historical chargeback and rebate rates and actual chargebacks and rebates claimed. The amount of actual chargebacks claimed and rebates paid could, however, be higher than the amounts we accrue, and could reduce our net revenues during the period in which claims are made. If we over- or under-estimate the level of chargebacks and rebates, there may be a material impact to our results of operations.

Health care reform or other changes in government regulation could harm our business.

The federal and state governments in the United States, as well as many foreign governments, from time to time explore ways to reduce medical care costs through health care reform. In the United States, the new presidential administration has indicated that it will advocate and seek reforms to the current health care system. Additionally, some parties have advocated for the re-importation of prescription drugs from Canada and other countries for resale in the United States at a discount to United States prices, as well as requiring the government to negotiate directly with drug companies for lower prices in the Medicare prescription drug plan. Due to the diverse range of proposals put forth from country to country and the uncertainty of any proposal s adoption, we cannot predict what impact any reform proposal ultimately adopted may have on the pharmaceutical industry or on our business, financial condition or results of operations.

We may be exposed to product liability claims and we cannot assure that our insurance will be adequate.

Like all pharmaceutical companies, the testing, manufacturing and marketing of our products may expose us to potential product liability and other claims resulting from their use. We, Novogyne and Novartis have been named as defendants in cases in which a plaintiff alleges personal injury from the use of HT products which we manufacture and Novogyne distributes. If any such claims against us or Novogyne are successful, we may be required to make significant payments and suffer the associated adverse publicity. Even unsuccessful claims could result in the expenditure of funds in litigation and the diversion of management time and resources. Novartis has indicated that it will seek

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indemnification from us and Novogyne to the extent permitted by the agreements between and among Novartis, Novogyne and us. We and Novogyne maintain product liability insurance, but we cannot assure that such insurance will cover all future claims or that we and/or Novogyne will be able to maintain existing coverage or obtain additional coverage at reasonable rates. In recent years, the cost of product liability insurance has increased while providing significantly less coverage and higher deductibles than in the past. If a claim is not covered or if coverage is insufficient, we and/or Novogyne may incur significant liability payments that would negatively affect our business, financial condition and results of operations. As of December 31, 2008, Novogyne s aggregate limit under its claims-made insurance policy was $10.0 million. Novogyne has established reserves in the amount of $9.0 million with an offsetting insurance receivable of $6.7 million for expected defense and settlement expenses as well as for estimated future cases alleging use of Noven s HT products. This accrual represents Novogyne management s best estimate as of December 31, 2008.

All of our transdermal products are manufactured at one location. An interruption of production at this facility could negatively affect our business, financial condition and results of operations.

All of our transdermal products are manufactured at a single facility in Miami, Florida. An interruption of manufacturing resulting from regulatory issues (including in connection with the FDA warning letter described above), technical problems, casualty loss (including due to a hurricane) or other factors could result in our inability to meet production requirements, which may cause us to lose revenues and which could have an adverse effect on our relationships with our partners and customers, any of which could have a material adverse effect on our business, financial condition or results of operations. Without our existing production facility, we would have no other means of manufacturing our transdermal products until we were able to restore the manufacturing capability at our facility or develop an alternative manufacturing facility. Although we carry business interruption insurance to cover lost revenues and profits resulting from casualty losses, this insurance does not cover all possible situations and all potential exposure and we cannot assure that any event of casualty to our facility would be covered by such insurance. The amount of our coverage may not be sufficient to cover the full amount of a covered loss. In addition, our business interruption insurance would not compensate us for the loss of opportunity and potential adverse impact on relations with our existing partners and customers resulting from our inability to produce transdermal products for them.

We use hazardous chemicals at our Miami manufacturing facility. Potential claims relating to improper handling, storage or disposal of these chemicals could be time consuming and costly.

Our research and development processes involve the controlled use of hazardous chemicals. These hazardous chemicals are reagents and solvents typically found in a chemistry laboratory. Our operations also produce hazardous waste products. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We cannot eliminate all risk of accidental contamination from or discharge of hazardous materials and any resultant injury. Compliance with environmental laws and regulations may be expensive. We might have to pay civil damages in the event of an improper or unauthorized release of, or exposure of individuals to, hazardous materials. We are not insured against these environmental risks.

Our insurance coverage may not be adequate and rising insurance premium costs could negatively affect our profitability.

We rely on insurance to protect us from many business risks, including product liability, business interruption, property and casualty loss, employment practices liability and directors and officers liability. The cost of insurance has risen significantly in the last few years,

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especially for property, business interruption and product liability coverage. These and other types of coverage also have become less widely available and more difficult to obtain. In response, we increased deductibles and decreased certain coverages to mitigate these costs while still paying higher premiums. We cannot assure that the insurance that we maintain and intend to maintain will be adequate, or that the cost of insurance and limitations in coverage will not adversely affect our business, financial condition or results of operations. Furthermore, it is possible that, in some cases, coverage may not be available at any price.

Our financial condition and results of operations could be harmed if we are required to perform under existing or future contractual indemnification provisions.

In the normal course of business, we enter into development, license, supply, employment and other agreements that include indemnification provisions. The Novogyne joint venture operating agreement contains an indemnification provision as do certain supply and license agreements between and among us, Novartis and Novogyne. The various indemnification provisions in these agreements are not uniform and, depending on the circumstances, may be subject to differing legal interpretations. As a consequence, it may be difficult in certain circumstances for us to determine or predict in advance what amounts we might be obligated to pay Novogyne or Novartis under these indemnification provisions or, alternatively, what obligations may be owed to us by these parties, including as they relate to potential damages, settlement amounts and defense costs associated with the product liability lawsuits that relate to the use of products we manufacture and Novogyne distributes. While insurance coverage may mitigate the costs of some of our obligations under our indemnification provisions, our business, financial condition and results of operations could be harmed if we are required to perform under these indemnification provisions and there is no, or insufficient, insurance coverage.

Our success depends on attracting and retaining our key employees.

Our success depends on our ability to attract and retain qualified, experienced personnel. We face significant competition in recruiting talented personnel. In the past, our Miami, Florida location, which is an area with relatively few pharmaceutical companies, made recruitment more difficult, as many candidates prefer to work in places with a broad pharmaceutical industry presence. The loss of key personnel, or the inability to attract and retain additional, competent employees, could adversely affect our business, financial condition or results of operations.

Our stockholders rights plan, our corporate charter documents, Delaware law and our joint venture operating agreement with Novartis may have an anti-takeover effect.

Our stockholders rights plan, our corporate charter documents, Delaware law and our joint venture operating agreement with Novartis each include provisions that may discourage or prevent parties from attempting to acquire us. These provisions may have the effect of depriving our stockholders of the opportunity to sell their stock at a price in excess of prevailing market prices in an acquisition of us. We have a stockholders rights plan, commonly referred to as a poison pill, which is intended to cause substantial dilution to a person or group who attempts to acquire us on terms that our Board of Directors has not approved. The existence of the stockholders rights plan could make it more difficult for a third party to acquire a majority of our common stock without the consent of our Board of Directors. Certain provisions of our certificate of incorporation and bylaws could have the effect of making it more difficult for a third party to acquire a majority of our

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outstanding voting common stock. These include provisions that limit the ability of stockholders to bring matters before an annual meeting of stockholders, call special meetings or nominate candidates to serve on our Board of Directors.

We are also subject to the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. For purposes of Section 203, a business combination includes a merger, asset sale or other transaction resulting in a financial benefit to the interested stockholder, and an interested stockholder is a person who, either alone or together with affiliates and associates, owns (or within the past three years, did own) 15% or more of the corporation s voting stock.

The Novogyne operating agreement has a buy/sell provision that either we or Novartis may trigger by notifying the other party of the price at which the triggering party would be willing to acquire the other party s interest in the joint venture. As a result of the buy/sell provision, any potential acquirer of us faces the possibility that Novartis could trigger this provision at any time and thereby require the acquirer to either purchase for cash Novartis interest in Novogyne (which would include the net present value of Novartis $6.1 million annual preferred return) or to sell its interest in Novogyne to Novartis. The existence of the buy/sell provision and the uncertainty it may create could discourage an acquisition of us by a third party, which could have an adverse effect on the market price for our common stock. In addition, the joint venture operating agreement gives Novartis the right to dissolve the joint venture in the event of a change in control of Noven if the acquirer is one of the ten largest pharmaceutical companies (as measured by annual dollar sales). Upon dissolution, Novartis would reacquire the rights to market Vivelle-Dot® subject to the terms of Novartis prior arrangement with us, and Novogyne s other assets would be liquidated and distributed between us and Novartis in accordance with our and Novartis respective capital account balances as determined pursuant to the joint venture operating agreement. This dissolution provision could discourage one of the ten largest pharmaceutical companies from attempting to acquire us, which could have an adverse effect on the market price for our common stock.

The market price for our common stock is volatile.

The market price for our common stock is volatile. During 2008, our common stock traded as low as $8.57 per share and as high as $14.28 per share. Any number of factors, including some that we do not control and some unrelated to our business or financial results, may have a significant impact on the market price for our common stock, including: announcements by us or our competitors of technological innovations or new commercial products; changes in governmental regulation; receipt by us or one of our competitors of regulatory approvals or adverse regulatory determinations; developments relating to patents or proprietary rights of us or one of our competitors; publicity regarding actual or potential medical results or risks for products that we or one of our competitors market or has under development; and period-to-period changes in financial results and the economy generally. We, like any other company with a volatile stock price, may be subject to securities litigation arising from significant downward movement in our stock price, which could have a material adverse effect on our business and financial results.

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The recent volatility in the financial markets and deteriorating economic conditions could adversely affect us or our partners, customers or suppliers.

As widely reported, financial markets in the United States, Europe and Asia have been experiencing extreme disruption in recent months, including, among other things, extreme volatility in securities prices, severely diminished liquidity and credit availability, rating downgrades of certain investments and declining valuations of others. Among other risks we face, the current tightening of credit in financial markets may adversely affect our ability to access our credit facility or obtain financing in the future, including, if necessary, to fund a product, technology or business acquisition. In addition, current economic conditions could harm the liquidity or financial position of our partners, customers or suppliers, which could in turn cause such parties to fail to meet their contractual or other obligations to us. Novogyne has currently recorded a product liability insurance receivable in the amount of $6.7 million due from a subsidiary of American International Group (AIG). Although AIG has advised that its commercial insurance subsidiaries remain well-capitalized despite the parent company s recent liquidity issues and diminished financial position, we cannot assure that the insurance carrier will pay the amounts that Novogyne believes are owed under the policy, either due to a change in the carrier s financial condition, a coverage dispute or otherwise.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Our headquarters and our manufacturing facility for our transdermal products are located on a 15-acre site in Miami-Dade County, Florida. On this site, we own an approximately 20,000 square foot building used for laboratory, office and administrative purposes. We also lease from Aventis, for $1.00 per year, seven acres of the site and two approximately 40,000 square foot buildings located on this portion of the site, which we use for manufacturing, engineering, administrative and warehousing purposes. The lease expires upon the earlier of 2024 or the termination or expiration of our 1992 license agreement with Aventis. This lease includes an option to purchase the leased facilities and property for its depreciated value and subsequent to year-end, we began the process of exercising this option and purchasing the facilities and properties for $1.00, its depreciated value as of December 31, 2008. The facility has been certified by the DEA to manufacture products containing controlled substances.

We lease approximately 17,600 square feet of office space in a neighboring facility for certain marketing and administrative functions and an additional 73,000 square feet of industrial space for warehousing which, depending on need, may also be used for manufacturing. The lease for the office space can be renewed by us until 2013. The initial lease term for the industrial space expires in 2015 and the term may be extended for up to an additional 21 years pursuant to four renewal options for five years each and a one-time option to renew for one year. Our site includes five acres of undeveloped land that we own, which we believe could accommodate new buildings for a variety of manufacturing, warehousing and developmental purposes. We believe that our facilities are in satisfactory condition, and are suitable for their intended use and have adequate capacity for the manufacture of our transdermal products.

In addition, as part of the Noven Therapeutics acquisition in August 2007, we assumed the operating lease of 8,700 square feet of office space that Noven Therapeutics used for their operations in New York, New York. This lease expires in September 2010.

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Our manufacturing facility for our transdermal products, as well as the site of our research and development activities and our corporate headquarters and other critical business functions, are located in an area subject to hurricane casualty risk. Although we have certain limited protection afforded by insurance, our business, earnings and competitive position could be materially adversely affected in the event of a major windstorm or other casualty.

Item 3. Legal Proceedings.

See Note 19 Commitments and Contingencies Litigation, Claims and Assessments, in the Notes to our Consolidated Financial Statements for information regarding legal proceedings.

Item 4. Submission of Matters to a Vote of Security Holders.

We did not submit any matters to a vote of stockholders during the quarter ended December 31, 2008.

Executive Officers of the Registrant

Set forth below is a list of the names, ages, positions held and business experience of the persons serving as our executive officers as of March 12, 2009. Officers serve at the discretion of the Board of Directors. There is no family relationship between any of our executive officers or between any of our executive officers and any of our directors, and there is no arrangement or understanding between any executive officer and any other person pursuant to which the executive officer was selected.

Peter Brandt. Mr. Brandt, age 51, was appointed to Noven s Board and to the offices of President and Chief Executive Officer in April 2008. From 1981 until 2007, Mr. Brandt served in a number of executive positions at Pfizer, Inc. (pharmaceuticals). He served as Pfizer s President U.S. Pharmaceuticals Operations from August 2006 until January 2007 and as its Senior Vice President U.S. Pharmaceuticals Operations from January 2006 to August 2006. From 2004 to 2006, Mr. Brandt served as President Latin America Operations and as Senior Vice President Worldwide Pharmaceuticals Finance, IT, Planning and Business Development, Pfizer Health Solutions. From 1998 to 2004, he served as Senior Vice President Worldwide Pharmaceuticals Finance, Planning and Business Development and Pfizer Health Solutions.

Jeffrey F. Eisenberg. Mr. Eisenberg, age 43, has been with Noven since November 1998 and, since January 2008, has served as Executive Vice President. From January 2008 to April 2008, he served as Noven s Interim Chief Executive Officer. From May 2005 to January 2008, he served as Noven s Senior Vice President Strategic Alliances. From January 2001 to September 2001, he served as Noven s Vice President, General Counsel and Corporate Secretary, and, from September 2001 to May 2005, he served as Noven s Vice President Strategic Alliances, General Counsel and Corporate Secretary. From 1995 through 1998, Mr. Eisenberg served as Associate General Counsel and then as Acting General Counsel of IVAX Corporation. Prior to joining IVAX, he was a lawyer in the corporate securities department of the law firm of Steel Hector & Davis.

Michael D. Price. Mr. Price, age 51, was appointed Vice President and Chief Financial Officer of Noven in November 2007. Mr. Price retired from Bentley Pharmaceuticals, Inc. in September 2006 and was retired since that time through joining Noven in November 2007. Prior to his retirement, Mr. Price served as Chief Financial Officer, Vice President/Treasurer and Secretary of Bentley, where he was employed from

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March 1992 until September 2006. Mr. Price also served on Bentley s Board of Directors from 1995 until 2004. Mr. Price is a Certified Public Accountant licensed by the State of Florida.

Steven M. Dinh. Mr. Dinh, age 53, was appointed Vice President and Chief Scientific Officer of Noven in June 2008. From 1997 to 2007, Mr. Dinh served in the dual role of Vice President of Research and Technology Development and Co-Chair Office of the President for Emisphere Technologies. Previously, he served as Chief Scientific Officer and Vice President of Research and Development for Lavipharm Laboratories, where he led research and development efforts in drug delivery and transdermal and cosmetic products. Prior to Lavipharm, he held several senior-level research and development positions focused in transdermal and pharmaceutical research and development for Novartis Pharmaceuticals Corporation and Ciba-Geigy.

Richard P. Gilbert. Mr. Gilbert, age 58, has served Noven as Vice President Operations since December 2004. From January 2000 to November 2004, he served as Vice President, Manufacturing Operations, at ConvaTec (a Bristol-Myers Squibb Company). Prior to ConvaTec, Mr. Gilbert held various senior roles at London International Group, LLC, The Tensar Corporation, and Richmond Technology.

Joel S. Lippman, M.D. Dr. Lippman, age 54, was appointed Vice President Clinical Development and Chief Medical Officer of Noven in July 2008. From 2006 to 2008, he served as an independent consultant to companies in the healthcare industry. From 2000 to 2006, Dr. Lippman served Ethicon, Inc., a Johnson & Johnson company, as Worldwide Vice President Medical Affairs and Chief Medical Officer and as a member of that company s Global Management Board. From 1990 to 2000, he served Ortho-McNeil Pharmaceutical, Inc., also a Johnson & Johnson company, as Vice President Clinical Trials. From 1988 to 1990, he served Wyeth-Ayerst Laboratories in a number of clinical development, medical affairs and related roles.

Anthony Venditti. Mr. Venditti, age 50, was appointed Vice President Marketing & Sales of Noven in June 2008. From 2005 to 2007, he served Novartis Pharmaceuticals Corporation as Vice President and head of Novartis United States Neuroscience division, where he was responsible for marketing, sales and new product operations for the central nervous system (CNS) portfolio in the United States. From 1996 to 2005, he served Novartis in a number of senior executive positions, with responsibility for marketing, sales, business analysis, strategic planning and new product commercialization, including key roles in the launch of several new products.

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PART II

Item 5. Market for Registrant s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Our Common Stock is listed on the Nasdaq Global Select Market and is traded under the symbol NOVN. As of March 2, 2009, we had 214 stockholders of record of our Common Stock. We have never declared a cash dividend on our Common Stock and do not anticipate declaring cash dividends in the foreseeable future. The following table sets forth, for the periods indicated, the high and low sale prices for our Common Stock as reported on the Nasdaq Global Select Market.

	High Price	Low Price
Fourth Quarter, 2008	$12.24	$ 9.45
Third Quarter, 2008	13.31	9.65
Second Quarter, 2008	12.97	8.57
First Quarter, 2008	14.28	8.98
Fourth Quarter, 2007	$16.88	$12.65
Third Quarter, 2007	24.06	14.99
Second Quarter, 2007	26.15	22.23
First Quarter, 2007	27.80	21.68

Stock Repurchase Program

The following table provides information with respect to our stock repurchases during the fourth quarter of 2008:

	Total Number of Shares Purchased	Average Price Paid Per Share	Total Number of Shares Purchased as Part of Publicly Announced Program	Approximate Dollar Value That May Yet be Purchased under the Program[1]
October 1, 2008 to October 31, 2008				$19,876,238
November 1, 2008 to November 30, 2008				19,876,238
December 1, 2008 to December 31, 2008				19,876,238
Totals				$19,876,238

1 In September 2007, we established a stock repurchase program authorizing the repurchase of up to $25.0 million of our common stock. During the

third quarter of 2007, Noven repurchased 322,345 shares of its common stock at an aggregate price of approximately $5.1 million. There is no expiration date specified for this program.

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Comparison of Five-Year Cumulative Total Return

The following graph and table show the cumulative total return, assuming the investment of $100 on December 31, 2003, on an investment in each of Noven s common stock, the Russell 2000 Index and the Value Line Drugs Index (in either case, assuming reinvestment of dividends). The comparisons in the graph and table are required by the SEC and are not intended to forecast or be indicative of possible future performance of our common stock. We have not declared dividends to our stockholders since our inception and do not plan to declare dividends in the foreseeable future. The following graph and chart are being furnished solely to accompany this Form 10-K pursuant to Item 201(e) of Regulation S-K and shall not be deemed soliciting materials or to be filed with the SEC (other than as provided in Item 201), nor shall such information be incorporated by reference into any of our filings under the Securities Act of 1933 or the Securities Exchange Act of 1934, whether made before or after the date hereof, and irrespective of any general incorporation language in any such filing.

Noven Pharmaceuticals, Russell 2000 Index and Value Line Value Line Drugs Index*
(Performance Results Through 12/31/08)

	2003	2004	2005	2006	2007	2008
Noven Pharmaceuticals	$100.00	$112.16	$ 99.47	$167.32	$ 91.26	$ 72.32
Russell 2000 Index	$100.00	$117.00	$120.88	$141.43	$137.55	$ 89.68
Value Line Drugs Index	$100.00	$ 99.10	$108.99	$125.53	$136.16	$123.67

Source: Value Line, Inc.

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Item 6. Selected Financial Data.

The selected financial data presented below is derived from our audited Consolidated Financial Statements. The data set forth below should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and the Consolidated Financial Statements and related notes appearing elsewhere in this Form 10-K (amounts in thousands, except per share amounts).

	Years Ended December 31,				
	2008[1,3]	2007[2,3]	2006[3]	2005[4]	2004
Consolidated Statement of Operations Data:					
Net Revenues:					
Product revenues, net	$ 77,627	$ 65,436	$ 48,326	$ 40,451	$ 36,871
License and contract revenues	30,548	17,725	12,363	12,081	9,020
Total net revenues	108,175	83,161	60,689	52,532	45,891
Costs and Expenses:					
Cost of products sold	51,861	41,017	36,508	34,047	20,514
Acquired in-process research and development		100,150			
Research and development	15,527	13,978	11,454	13,215	9,498
Selling and marketing	23,299	9,160	967	563	624
General and administrative	36,796	30,411	20,734	16,352	16,647
Total costs and expenses	127,483	194,716	69,663	64,177	47,283
Reversal of contingent milestone liability	5,000				
Loss from operations	(14,308)	(111,555)	(8,974)	(11,645)	(1,392)
Equity in earnings of Novogyne	45,642	35,850	28,632	24,655	17,641
Interest and other income, net	2,022	5,454	4,272	2,242	999
Loss on auction rate securities	(515)				
Income (loss) before income taxes	32,841	(70,251)	23,930	15,252	17,248
Provision (benefit) for income taxes	11,429	(24,875)	7,942	5,280	6,024
Net income (loss)	$ 21,412	$ (45,376)	$ 15,988	$ 9,972	$ 11,224
Basic earnings (loss) per share	$ 0.87	$ (1.84)	$ 0.67	$ 0.42	$ 0.48
Diluted earnings (loss) per share	$ 0.87	$ (1.84)	$ 0.66	$ 0.42	$ 0.46

Weighted average number of common shares outstanding:					
Basic	24,617	24,728	23,807	23,566	23,332
Diluted	24,729	24,728	24,252	23,981	24,305

Refer to footnotes on the following page.

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	As of December 31,				
	2008[1,3]	2007[2,3]	2006[3]	2005[4]	2004
Consolidated Balance Sheet Data:					
Current Assets:					
Cash and cash equivalents	$ 62,875	$ 13,973	$ 9,144	$ 66,964	$ 93,958
Short-term investments available-for-sale, at fair value	3,650	21,565	144,455	17,900	
Other current assets	47,113	45,565	56,608	34,746	48,763
Non-current Assets:					
Property, plant and equipment, net	34,886	36,213	37,010	34,455	22,587
Investments in auction rate securities	11,810	32,835			
Investment in Novogyne	24,319	24,310	23,296	23,243	26,233
Net deferred income tax asset, non-current portion	65,159	58,053	8,308	6,373	8,239
Intangible assets, net[5]	36,508	38,773	2,317	2,211	2,174
Goodwill[5]	14,407	14,734			
Deposits and other non-current assets	839	677	227	18	21
Total assets	$ 301,566	$ 286,698	$ 281,365	$ 185,910	$ 201,975
Current liabilities	$ 62,994	$ 57,079	$ 29,386	$ 28,488	$ 45,372
Non-current liabilities:					
Long-term obligations, less current portion	27	8,438	279		121
Deferred license and contract revenues, non-current portion	77,112	85,056	74,188	16,053	27,443
Other non-current liabilities	997	1,831	837	748	
Total liabilities	$ 141,130	$ 152,404	$ 104,690	$ 45,289	$ 72,936
Stockholders equity	$ 160,436	$ 134,294	$ 176,675	$ 140,621	$ 129,039

[1] Financial results for 2008 included: (i) the recognition of $7.2 million of previously deferred license and contract revenues as a result of the termination of our agreements with Shire for

the development of an amphetamine patch, (ii) the recognition of $5.0 million in operating income from the reversal of an accrued liability related to a future Pexeva® contingent sales milestone, (iii) $3.7 million of charges associated with the voluntary market withdrawal of a portion of the Daytrana® product by Shire, (iv) a $3.8 million charge related to previously manufactured Daytrana® product at risk of exceeding the product s peel force specification during its shelf life, and (v) a $1.8 million charge related to a patent infringement case.

[2] Financial results for 2007 included: (i) a $100.2 million charge recorded in the 2007 third quarter for the portion of the Noven

Therapeutics acquisition purchase price allocated to in-process research and development; (ii) a $3.3 million charge associated with the voluntary withdrawal of a portion of Daytrana® product by Shire; (iii) a $3.3 million fourth quarter charge related to separation arrangements with certain executive officers; and (iv) results of operations of Noven Therapeutics from the date of acquisition (August 14, 2007) through December 31, 2007.

[3] Financial results for 2008, 2007 and 2006 included $4.8 million, $5.4 million and $3.3 million, respectively, in stock-based compensation expenses resulting from the adoption of SFAS No. 123 (R),

Share-Based Payment effective January 1, 2006.

4 Financial results for 2005 included $9.9 million in charges associated with the write-off of fentanyl inventories and associated destruction charges, and the recognition of $5.7 million in fentanyl deferred license revenues, resulting from the FDA s decision not to approve our application for a generic fentanyl patch.

5 Intangible assets, net and goodwill increased in 2007 as a result of the Noven Therapeutics acquisition on August 14, 2007.

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Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations.

This section addresses material aspects of Noven s consolidated financial condition and results of operations. The contents of this section include:

An executive summary of our 2008 consolidated results of operations;

A review of certain items that may affect the historical or future comparability of our consolidated results of operations;

An analysis of our consolidated results of operations and our liquidity and capital resources;

An outlook that includes our current financial guidance for 2009;

A discussion of how we apply our critical accounting estimates; and

A discussion of recently-issued accounting standards.

This discussion should be read in conjunction with Noven and Novogyne s 2008 financial statements and the related notes thereto included in this Form 10-K.

Executive Summary

The following Executive Summary is qualified in its entirety by the more detailed discussion and analysis of our financial condition and results of operations appearing in this Item 7 as well as in our consolidated financial statements and related notes included in this Form 10-K.

Our financial results for 2008 included a full year of the results of operations of Noven Therapeutics (previously known as JDS Pharmaceuticals), a specialty pharmaceutical company that we acquired on August 14, 2007. Our financial results included the results of operations of Noven Therapeutics beginning on the acquisition date (August 14, 2007). Noven Therapeutics is a specialty pharmaceutical company focused in CNS and women s health indications, with a targeted sales force, three marketed psychiatry products, and a non-hormonal product for vasomotor symptoms in clinical development. The Noven Therapeutics acquisition was an important part of Noven s transition from primarily a transdermal drug delivery company to an integrated specialty pharmaceutical company.

Our financial results for 2008 also included: (i) the recognition of $7.2 million of previously deferred license revenues as a result of the termination of our agreements with Shire for the development of an amphetamine patch; (ii) the recognition of $5.0 million in operating income due to the reversal of an accrued liability related to a future Pexeva® contingent sales milestone; (iii) $3.7 million in charges for reimbursements to Shire for voluntary recalls of certain Daytrana® product initiated by Shire in 2008, as well as the establishment of a $3.8 million reserve related to previously-manufactured Daytrana® product at risk of exceeding the product s peel force specification during its shelf life (this aggregate $7.5 million amount is referred to as the 2008 Daytrana® Charges); and (iv) a $1.8 million charge related to a patent infringement case.

Our financial results for 2007 included: (i) a $100.2 million charge for the portion of the Noven Therapeutics purchase price allocated to in-process research and development (the IPR&D Charge); (ii) a $3.3 million charge for reimbursements to Shire for voluntary recalls of certain Daytrana® product (the 2007 Daytrana® Charges); and (iii) an aggregate $3.3 million charge related to separation arrangements associated with the retirement of certain former executive officers.

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Including the impact of these items, we reported net income of $21.4 million ($0.87 diluted earnings per share) for 2008 compared to a net loss of $45.4 million ($1.84 loss per share) for 2007. Our net revenues in 2008 were $108.2 million, an increase of 30% compared to $83.2 million reported in 2007. This increase reflects the recognition of $24.5 million in net revenues associated with Noven Therapeutics, primarily due to our sales of Pexeva® and Lithobid® products as well as increased license and contract revenues, primarily due to the $7.2 million recognized as a result of the termination of certain of our agreements with Shire, as discussed above, in addition to increased amortization of deferred revenue from Daytrana® sales milestone payments. The increase in net revenues was partially offset by a $1.6 million reduction in revenues for 2008, representing a portion of the 2008 Daytrana® Charges.

Gross margin, as a percentage of net product revenues, was 33% in 2008 compared to 37% in 2007. Cost of products sold in 2008 included $1.1 million of the 2008 Daytrana® Charges, $2.8 million of inventory write-offs primarily related to an equipment failure in transdermal manufacturing, as well as increased quality assurance activities and expenses, primarily related to Daytrana® production. Although we implemented new manufacturing processes that helped improve efficiencies associated with existing Daytrana® production in the fourth quarter of 2008, we expect the peel force issue to continue to negatively affect margins as a result of increased Daytrana® manufacturing costs, including reimbursements to Shire for the active methylphenidate ingredient (AMI) included in destroyed product, unless and until the peel force issue is resolved.

Excluding the $100.2 million IPR&D Charge in 2007, research and development expenses in 2008 increased $1.5 million to $15.5 million compared to 2007. Selling and marketing expenses increased to $23.3 million from $9.2 million in 2007, reflecting a full year of selling and marketing expenses at Noven Therapeutics, including $4.8 million related to Stavzor®, which was commercially launched in August 2008. In 2008, general and administrative expenses increased $6.4 million, or 21%, reflecting $4.8 million of the 2008 Daytrana® Charges (compared to $2.2 million in 2007), a full year of expenses at Noven Therapeutics, and a $1.8 million charge related to a patent infringement case.

We recognized $45.6 million in earnings from Novogyne in 2008, an increase of 27% compared to 2007. Net revenues at Novogyne increased 15% to $169.6 million in 2008, primarily due to increased sales of Vivelle-Dot®. Novogyne s gross margin percentage for 2008 increased slightly to 80%. Novogyne s selling, general and administrative expenses were $37.5 million in 2008, a 2% decrease from 2007. Novogyne s net income for 2008 increased 25% to $99.5 million compared to $79.8 million in the prior year.

At December 31, 2008, we had $62.9 million in cash and cash equivalents and $15.5 million in investments in auction rate securities. This compares with $14.0 million in cash and cash equivalents and $54.4 million in investments in auction rate securities at December 31, 2007. In the third quarter of 2008, we received the third and final $25.0 million milestone payment related to Shire s sales of Daytrana®. As of December 31, 2008, no amounts were outstanding under our $15.0 million revolving credit facility.

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Our investments in auction rate securities at December 31, 2008 had a fair value of $15.5 million. We liquidated $39.0 million of these investments at par value in 2008. The auction rate securities that we hold are collateralized primarily by tax-exempt municipal bonds and, to a much lesser extent, guaranteed student loans. During 2008, we recorded an other-than-temporary change in fair value of $0.5 million relating to our investments in auction rate securities, which was consequently recognized in our 2008 Consolidated Statement of Operations.

Total prescriptions for Vivelle-Dot® increased 6% in 2008 compared to 2007, and total prescriptions for Novogyne s HT products, taken as a whole, increased 3%. By comparison, the United States HT market declined 5% for the same period. Total prescriptions for Daytrana® decreased 11% in 2008 compared to 2007, while prescriptions for ADHD stimulant therapies as a class increased 8% over the same period. Total prescriptions for Pexeva® decreased 6% in 2008 compared to 2007, while for the same period prescriptions for the selective serotonin re-uptake inhibitor (SSRI) class increased 1%. Reflecting ongoing generic substitution, total prescriptions for Lithobid® decreased 31% in 2008 compared to 2007.

In July 2008, the FDA granted final approval of the New Drug Application for Stavzor® (valproic acid delayed release capsules) in the treatment of manic episodes associated with bipolar disorder, adjunctive therapy in multiple seizure types (including epilepsy), and prophylaxis of migraine headaches. Noven Therapeutics commercially launched Stavzor® in August 2008.

In August 2008, we entered into global license and supply agreements with Procter & Gamble Pharmaceuticals, Inc. relating to the development and commercialization of a low-dose testosterone patch for the treatment of HSDD and other indications.

In the fourth quarter of 2008, we began patient enrollment for a Phase 2 study of Mesafem, our developmental non-hormonal product for vasomotor symptoms (hot flashes), and that study is continuing, with completion expected during 2009.

Also in the fourth quarter of 2008, we terminated our agreements with Shire for the development of an amphetamine patch, and the rights to this product were returned to us. We intend to pursue the further development and commercialization of the product. As a result of the termination, we recognized $7.2 million of previously deferred payments from Shire as license revenues in the fourth quarter of 2008.

Certain Items that May Affect Historical or Future Comparability

Set forth below are certain items that may affect the historical or future comparability of our consolidated results of operations and financial condition. Such disclosure is not intended to address every item that may affect the historical or future comparability of our consolidated results of operations or financial condition and such disclosure should be read in conjunction with the discussion and analysis of our consolidated results of operations, liquidity and capital resources and outlook appearing elsewhere in this Item 7.

Acquisition of Noven Therapeutics, LLC in 2007

As more fully described in Note 4 Acquisition of Noven Therapeutics, LLC to the Consolidated Financial Statements, we acquired Noven Therapeutics, LLC (f/k/a JDS Pharmaceuticals, LLC) on August 14, 2007 (the Closing Date). The results of operations of Noven Therapeutics have been included in our consolidated results beginning on the Closing Date. The total purchase price for the Noven Therapeutics acquisition consisted of $125.0 million cash paid at closing, approximately $5.4 million of transaction costs consisting

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primarily of fees paid for financial advisory, legal, valuation and accounting due diligence services, approximately $0.5 million in connection with non-competition agreements entered into with two executives of Noven Therapeutics in connection with the acquisition and $1.0 million of net working capital adjustments. We funded the acquisition from the sale of short-term investments. We accounted for the acquisition of Noven Therapeutics using the purchase method of accounting. The final purchase price exceeded the amounts allocated to the tangible and intangible assets acquired and liabilities assumed by approximately $14.4 million, which has been recorded as goodwill, all of which is deductible for tax purposes.

The final allocation of total purchase price for the acquisition to tangible and intangible assets acquired and liabilities assumed was based on their estimated fair values at the Closing Date, which increased our assets and liabilities on the Closing Date as follows (amounts in thousands):

Property, equipment and other assets	$ 525
Intangible assets:	
Acquired in-process research and development	100,150
Identifiable intangible assets	39,110
Goodwill	14,407
Net working capital, including cash of $0.6 million	(7,062)
Long-term obligation assumed	(3,711)
Contingent milestones assumed	(11,500)
Total purchase price	$ 131,919

The $100.2 million of the purchase price allocated to IPR&D was charged to operations immediately following the completion of the acquisition in 2007. The IPR&D expense resulted in a significant loss in 2007.

The assumed long-term obligation of $3.7 million was paid in 2007 based on an analysis of favorable early payment discount. The $11.5 million contingent milestones assumed were for contingent sales milestones payable upon the achievement of specified future sales levels of Pexeva®. We became obligated to pay $6.5 million of these milestones based on 2007 and 2008 sales of Pexeva®. In the third quarter of 2008, we recognized $5.0 million in operating income as a result of the reversal of the remaining accrued liability upon our determination that the achievement of the applicable milestone was no longer probable based on projected sales of Pexeva®.

Daytrana®

Daytrana® is our transdermal methylphenidate system for the treatment of ADHD, which we have licensed globally to Shire. We and Shire have received reports from some consumers concerning the difficulty of removing the release liner from certain Daytrana® patches. In the first quarter of 2007, we, together with Shire, implemented enhancements to the Daytrana® release liner. While the enhanced release liner has reduced the level of consumer reports, some patients and caregivers continue to have difficulty in removing the release liner from some Daytrana® patches.

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In July 2007, we received from the FDA a list of observations on Form 483 following an on-site inspection of our manufacturing facilities. The majority of the observations in the Form 483 related to the Daytrana® patch and difficulties experienced by some patients in removing the release liner, including certain product lots that utilize the enhanced release liner. In July 2007, we submitted to the FDA our response to the Form 483.

In the third quarter of 2007, Shire initiated two voluntary recalls of a portion of the Daytrana® product on the market primarily in response to feedback from patients and caregivers who experienced difficulty removing the release liner from some Daytrana® patches. We paid Shire $3.3 million in February 2008 related to those recalls. This payment was charged to operations in 2007.

In January 2008, we received a warning letter from the FDA in connection with the FDA s July 2007 inspection of our manufacturing facilities. In the warning letter, which is posted at the FDA s website, the FDA cited Current Good Manufacturing Practice deficiencies related to: (i) peel force specifications for removal of Daytrana ® s release liner; and (ii) data supporting the peel force characteristics of Daytrana ® enhanced release liner throughout the product s shelf life. We submitted our response to the warning letter on January 30, 2008, which remains under review by the FDA.

In April 2008, a Noven stability protocol identified certain Daytrana® lots exhibiting high peel force characteristics. In June 2008, Shire initiated the voluntary recall of two lots of Daytrana® that did not meet the product s release liner removal specification. In August 2008, Shire initiated the voluntary recall of two additional lots of Daytrana® that did not meet the product s release liner removal specification. During 2008, we paid Shire $3.7 million related to its June and August 2008 recalls, of which approximately $3.1 million has been charged to general and administrative expenses, $0.4 million was recorded as a reduction in revenues and $0.2 million was charged to cost of products sold in 2008. For each of the recalls described above, the amount charged to general and administrative expenses represents amounts we are obligated to reimburse Shire for direct costs of the recalls, the amounts reflected as reductions of revenue represent the amounts recognized for product which is expected to be returned and the charge to cost of product sold represents the value of AMI included in such product for which we are required to reimburse Shire.

In the fourth quarter of 2008, we implemented new product release testing intended to predict which Daytrana® lots are at risk of developing peel force issues during the product s shelf life. Product that fails to meet this test will be destroyed, which will result in increased Daytrana® manufacturing costs, including reimbursements to Shire for the AMI included in the destroyed product. In 2008, Daytrana® cost of products sold exceeded our Daytrana® net revenues by $7.0 million, including $2.7 million of the 2008 Daytrana® Charges, of which $1.6 million was recorded as a reduction in revenues and $1.1 million was charged to cost of products sold. Although we have implemented new manufacturing processes that helped improve efficiencies associated with existing Daytrana® production in the fourth quarter of 2008, we expect the peel force issue to continue to negatively affect margins as a result of increased Daytrana® manufacturing costs, including reimbursements to Shire for the AMI included in destroyed product, unless and until the peel force issue is resolved.

In accordance with SFAS No. 5, we have determined that certain previously-manufactured lots that would not have met the new release testing standard are probable of being voluntarily withdrawn or recalled from the market prior to the expiration of their shelf life.

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Consequently, during 2008, we established a reserve of $3.8 million related to these affected lots, which includes $1.7 million of estimated recall costs that we will be required to reimburse Shire if there are withdrawals or recalls. Of the $3.8 million reserve, approximately $1.7 million has been charged to general and administrative expenses, $1.2 million was recorded as a reduction in revenues and $0.9 million was charged to cost of products sold. We do expect that there will be an additional voluntary withdrawal/recall of some Daytrana® lots due to the peel force issue. While we believe the $3.8 million reserve is adequate for the costs of such withdrawal/recall, we cannot assure that our costs related to this issue will not exceed the amount reserved. Although the new release testing is designed to reduce the likelihood that newly-manufactured product will be withdrawn or recalled in the future, we cannot assure that our testing procedures will detect all production issues or that there will not be future Daytrana® market withdrawals or recalls.

In January 2009, we received from the FDA a list of observations on Form 483 following an on-site inspection of our manufacturing facilities. Like the warning letter and the prior Form 483, the majority of the observations in the Form 483 relate to the manufacture of Daytrana® product that exhibits high peel force characteristics, an issue which Noven and Shire continue to work to resolve.

We believe we have identified the root cause of the peel force issue. We are testing manufacturing solutions designed to address the peel force issue. Implementation of the solutions being tested will require prior agreement from the FDA. Subject to FDA review and agreement, Noven s current plan calls for shipments to Shire in the third or fourth quarter of 2009. We cannot assure that the FDA will approve the solutions being tested on a timely basis or at all. Noven s warning letter remains under review by the FDA.

For a detailed discussion of the risks and uncertainties facing Daytrana®, please see the risk factor discussion beginning on page 21 of this Form 10-K.

Results of Operations

As discussed in Note 17 Segment and Customer Data to our Consolidated Financial Statements, we operate in three segments distinguished along product categories and nature of the business unit: (i) Noven Transdermals, which currently engages in the manufacturing, licensing and sale to partners of prescription transdermal products; (ii) Novogyne, our women s health joint venture with Novartis in which we own a 49% equity interest; and (iii) Noven Therapeutics, which currently engages in the marketing and sale of pharmaceutical products.

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Revenues:

The following table summarizes our net revenues by segment and type for our operating segments which generate revenues (dollar amounts in thousands):

	Years Ended December 31,				
	2008	% Change	2007	% Change	2006
Noven Transdermals					
Novogyne:					
Product sales	$ 21,308	-5%	$ 22,425	14%	$ 19,714
Royalties	8,411	13%	7,458	9%	6,845
Product revenues Novogyne	29,719	-1%	29,883	13%	26,559
Third Parties:					
Product sales	23,100	-11%	26,000	21%	21,422
Royalties	334	-2%	340	-1%	345
Product revenues third parties	23,434	-11%	26,340	21%	21,767
Total product revenues	53,153	-5%	56,223	16%	48,326
License and contract revenues	30,548	72%	17,725	43%	12,363
Total Transdermals	83,701	13%	73,948	22%	60,689
Noven Therapeutics					
Third Parties:					
Product sales	24,474	166%	9,213	N/M	
Net Revenues	$ 108,175	30%	$ 83,161	37%	$ 60,689

N/M Not Meaningful

Net Revenues

As described in more detail below, the 30% increase in net revenues for 2008 as compared to 2007 was primarily attributable to the addition of $24.5 million in net revenues reflecting a full year of sales of Noven Therapeutics products, as compared to 4.5 months of sales in 2007. We also realized a $12.8 million, or 72%, increase in license and contract revenues compared to 2007, which was primarily attributable to an increase in amortization of Daytrana® milestones and $7.2 million of revenue recognized upon termination of an amphetamine development agreement in the fourth quarter of 2008. These increases were partially offset by a $3.1 million decrease in product revenues from our Noven Transdermals segment comprised primarily of a $2.6 million decrease in sales of Daytrana® in 2008.

As described in more detail below, the 37% increase in net revenues for 2007 as compared to 2006 was primarily attributable to full year sales of Daytrana® and an increase in license revenue associated with that product. Aggregate sales to Novogyne increased primarily due to increased sales of Vivelle-Dot®. In addition, revenues in 2007 benefited from the inclusion of $9.2 million in Pexeva® and Lithobid® sales since August 14, 2007, the date of

our acquisition of Noven Therapeutics.

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Product Revenues Novogyne

Product revenues Novogyne consists of our sales of Vivelle-Dot®/Estradot® and CombiPatch® to Novogyne at a fixed price for resale and product sampling by Novogyne primarily in the United States as well as the royalties we receive as a result of Novogyne s sales of Vivelle-Dot®. For additional information on the components of product revenues Novogyne as well as our other sources of revenues, see Critical Accounting Estimates Revenue Recognition.

The $0.2 million decrease in product revenues from Novogyne for 2008 compared to 2007 primarily resulted from a $1.5 million decline of Vivelle-Dot® product revenues, partially offset by an increase of $1.0 million in royalties due to increased sales by Novogyne to its customers for 2008, as well as a $0.5 million increase in unit sales of CombiPatch® due to the timing of orders from Novogyne. The decline in Vivelle-Dot® product revenues is attributable to the timing of orders as prescriptions have increased period to period. The previously disclosed backlog of orders due to the first quarter 2008 production issues was completely filled as of December 31, 2008.

The $3.3 million increase in product revenues from Novogyne for 2007 compared to 2006 primarily related to a $3.9 million increase in sales of Vivelle-Dot®, of which $1.9 million related to trade product sales due to increased prescription trends, $0.9 million related to the timing of orders from Novogyne for samples of Vivelle-Dot® and $1.1 million related to a price increase. Royalties increased $0.6 million due to increased sales by Novogyne for 2007.

As noted below under Novogyne Net Revenues , Novogyne sells its products to trade customers, including wholesalers, distributors and chain pharmacies and the timing of orders by these customers is difficult to predict and can lead to significant variability in trade customers ordering patterns. As a result, there may be significant period-to-period variability in Novogyne s ordering patterns from Noven.

Product Revenues Third Parties

Product revenues third parties consist of: (i) sales of Estradot®, Estalis® and Menorest hormone therapy patches to Novartis Pharma at a price based on a percentage of Novartis Pharma s net selling price (subject to certain minima) for resale primarily outside the United States and Japan, together with royalties generated from Novartis Pharma s sales of Estradot® in Canada; (ii) sales of Daytrana® to Shire for commercial resale in the United States; (iii) beginning on August 14, 2007, Noven s commercial sales of Pexeva® and Lithobid® to trade customers, including wholesalers, distributors and chain pharmacies; and (iv) beginning in August 2008, sales of Stavzor® to trade customers, including wholesalers, distributors and chain pharmacies.

As discussed above, the increase in net revenues for 2008 compared to 2007 for our Noven Therapeutics segment was primarily attributable to $24.5 in net revenues in 2008 reflecting a full year of sales compared to $9.2 million in net revenues in 2007, reflecting only 4.5 months of sales following the Noven Therapeutics acquisition.

The $2.9 million decrease in product revenues third parties in our Noven Transdermals segment for 2008 compared to 2007 primarily consisted of a $2.6 million decline in sales of Daytrana® and a $0.6 million decline in third-party revenues from our HT products due to a decrease in pricing. The decrease in Daytrana® product revenues was largely attributable to delays in the release of product in 2008, an aggregate $1.6 million reduction in revenues related to expected Daytrana® product returns due to peel force issues on sold product, the timing of orders and, to a lesser extent, decreased demand. In addition, Noven realized a lower benefit from price increases for our third party HT product through periodic price reconciliation payments received from Novartis as further described below. We recognized $2.4 million and $3.1 million of such payments in 2008 and 2007, respectively.

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The $4.6 million increase in product revenues third parties in our Noven Transdermals segment for 2007 compared to 2006 primarily related to $4.7 million increase in volume sales of Daytrana® and a $1.3 million increase related to HT product pricing with Novartis Pharma. Daytrana® product sales in 2007 were $13.4 million compared to $8.6 million in 2006. Sales of Daytrana® commenced in the second quarter of 2006. The increase related to HT product pricing was primarily due to the recognition of a higher price reconciliation payment received from Novartis Pharma in 2007 compared to 2006. Noven records such payments from time to time upon Novartis Pharma s determination that its actual sales price of our product entitles us to receive amounts in excess of the minimum transfer price at which we initially sold the product to Novartis Pharma. These increases were partially offset by declines of $0.7 million and $0.5 million in sales volume of Menorest and Femiest®, respectively. The decline in Menorest is attributable to the continued transition from Menorest to Estradot®, while we believe the decline in Femiest® was due to the timing of orders.

We sell Stavzor® to pharmaceutical wholesalers and chain drug stores. These companies have the right to return Stavzor® for up to one year after product expiration. As a result of the commercial launch of Stavzor® in the third quarter of 2008, we do not have sufficient sales history to reasonably estimate product returns. Under SFAS No. 48, we cannot recognize revenue on product shipments until we can reasonably estimate returns relating to these shipments. In accordance with SFAS No. 48, we defer recognition of revenue on product shipments of Stavzor® to our customers until such time as Stavzor® units are dispensed through patient prescriptions, since our customers are no longer permitted to return the product once it has been dispensed. We estimate the volume of prescription units dispensed at pharmacies based on data provided by external, independent sources. These sources poll pharmacies, hospitals, mail order and other retail outlets for Stavzor® prescriptions and project this sample on a national level. We will recognize revenue based on prescription units dispensed until we have sufficient sales history to reasonably estimate product returns. We recognized $0.4 million of net revenues for Stavzor® in 2008, and $1.5 million remained in deferred product revenue on our Consolidated Balance Sheet as of December 31, 2008.

License and Contract Revenues

License revenues consist of the recognition of non-refundable up-front, milestone and similar payments under license agreements. Contract revenues consist of the recognition of payments received as work is performed on research and development projects. The payments received may take the form of non-refundable up-front payments, payments received upon the completion of certain phases of development work and success milestone payments.

License and contract revenues increased $12.8 million for 2008 compared to 2007, primarily due to (i) a $4.8 million increase in amortization of milestone payments received from Shire related to the license of Daytrana®; (ii) $7.2 million related to the termination of the amphetamine patch project with Shire as described below; and (iii) an $0.8 million increase in contract revenues due to additional work performed on developmental products. The $4.8 million increase in amortization of milestone payments reflects a full year of amortization of the second $25.0 million Daytrana® sales milestone payment received during the third quarter of 2007 and additional amortization of the third $25.0 million Daytrana® sales milestone payment received in the third quarter of 2008.

In connection with our collaboration with Shire for the development of an amphetamine patch, Shire paid us an aggregate $7.2 million, including payments for development and for the exclusive developmental rights to the product. These $7.2 million of payments received were included in deferred license and contract revenues on our Consolidated Balance Sheet as of December 31, 2007.

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On November 5, 2008, we entered into a letter agreement (the Termination Agreement) with Shire terminating our agreements with Shire relating to an amphetamine patch. The Termination Agreement terminates the amphetamine collaborative agreements with Shire dated as of (i) June 15, 2004, (ii) May 4, 2007, and (iii) June 4, 2007. Under the Termination Agreement, rights to the developmental amphetamine patch were returned to us. We currently intend to pursue the further development and commercialization of the product. Shire will be entitled to a modest royalty if we elect to commercialize a product that incorporates intellectual property arising from the development project with Shire. As a result of the termination of this project with Shire, we recognized the $7.2 million as license and contract revenues in the fourth quarter of 2008.

License revenues increased $6.9 million for 2007 compared to 2006, which is primarily attributable to an increase of $8.1 million in amortization of milestone payments received from Shire related to the license of Daytrana®. The $8.1 million increase reflects full-year amortization of the $50.0 million approval milestone compared to two quarters in 2006, full-year amortization of the $25.0 million sales milestone received in the first quarter of 2007 as well as six-months amortization of the $25.0 million sales milestone received in the third quarter of 2007. In 2006, we benefited from the recognition of $1.0 million in deferred license revenues related to a one-time non-refundable payment from a third party. Contract revenues declined $1.5 million for 2007 compared to 2006, primarily reflecting a decline in contract work performed.

Gross to Net Revenues

We record revenues net of sales allowances for rebates, chargebacks, cash and other discounts, as well as sales returns allowances. Sales returns allowances represent management s best estimate of the amount of product shipped to customers that will be returned in the future. Such estimates consider a variety of factors which can differ depending on the nature of the product, customer sales terms and historical return rates. Our Transdermal products are generally sold to partners and are typically not subject to return based on expiration dating. However, the products are subject to return based on manufacturing and quality specifications and, therefore, may be subject to product recall. We establish return allowances on product sold through our Transdermals segment when it is probable that such product will be recalled or withdrawn. Sales returns allowances in our Noven Therapeutics segment represent allowances for estimated product returns based on expiration dating and are estimated based on historical return rates, current sales levels and other factors on a product-by-product basis. During each of 2008 and 2007, sales returns allowances for Noven Transdermals increased $0.7 million primarily due to Shire s voluntary recalls of certain Daytrana® product. For the Noven Therapeutics segment, during 2008, allowances for Medicaid, Medicare & State program rebates and credits including redemption offers decreased 4% as a percentage of revenue due to the non-renewal of certain unprofitable state Medicaid contracts. Sales returns allowances for the Noven Therapeutics segment increased 4% due to an increase in actual returns of Pexeva® and Lithobid® product. All other sales allowances for the Noven Therapeutics segment were consistent in 2008 and 2007, as a percentage of revenue.

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The following table sets forth the reconciliation of our gross revenues to net revenues (dollar amounts in thousands):

	Years Ended December 31,					
	2008	% of gross revenues	2007	% of gross revenues	2006	% of gross revenues
Noven Transdermals:						
Gross revenues	$ 85,317	100%	$ 74,903	100%	$ 60,982	100%
Sales returns allowances	(1,616)	-2%	(955)	-1%	(293)	0%
Net revenues	$ 83,701	98%	$ 73,948	99%	$ 60,689	100%
Noven Therapeutics:						
Gross revenues	$ 39,196	100%	$ 14,579	100%		
Cash discounts	(835)	-2%	(285)	-2%		
Medicaid, Medicare & State program rebates and credits including redemption offers	(7,285)	-19%	(3,289)	-23%		
Chargebacks	(1,315)	-3%	(351)	-2%		
Wholesaler fees	(1,877)	-5%	(775)	-5%		
Sales returns allowances	(3,410)	-9%	(666)	-5%		
Sales and returns allowances	(14,722)	-38%	(5,366)	-37%		
Net revenues	$ 24,474	62%	$ 9,213	63%		

Gross Margin

This section discusses gross margins relating to our product revenues: (i) across all of our products (Overall Gross Margin); (ii) on our transdermal product revenues from Novogyne (Gross Margin Novogyne), which for accounting purposes is considered a related party; (iii) on our transdermal product revenues from third parties (Gross Margin Third Parties); and (iv) on our Noven Therapeutics products. Product revenues from third parties include HT product sales to Novartis Pharma for resale primarily outside the United States and Japan, as well as Daytrana® product sales to Shire. Noven Therapeutics product revenues include sales of Stavzor®, Pexeva® and Lithobid® to trade customers.

For our Noven Transdermals segment, the allocation of manufacturing expenses impacts our determination of inventory costs and, consequently, gross margins for each of our products. Manufacturing expenses, which totaled $31.0 million, $25.9 million and $26.2 million in 2008, 2007 and 2006, respectively, include compensation and benefits, supplies and tools, equipment costs, depreciation and amortization, and insurance costs and represent a substantial portion of our inventory production costs. The allocation of manufacturing expenses among manufactured products requires us to make significant estimates that involve subjective and often complex judgments. Using different estimates would likely result in materially different results for Gross Margin Novogyne and Gross Margin Third Parties than are presented in the gross margin table below.

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Our gross margins are summarized as follows (dollar amounts in thousands):

	Years Ended December 31,					
	2008		2007		2006	
Noven Transdermals						
Novogyne:						
Product revenues	$ 29,719		$ 29,883		$ 26,559	
Cost of products sold	15,134		13,683		14,102	
Gross profit	14,585	49%	16,200	54%	12,457	47%
Third parties:						
Product revenues	23,434		26,340		21,767	
Cost of products sold	28,689		24,188		22,406	
Gross profit (loss)	(5,255)	-22%	2,152	8%	(639)	-3%
Total Noven Transdermals						
Product revenues	53,153		56,223		48,326	
Cost of products sold	43,823		37,871		36,508	
Gross profit	9,330	18%	18,352	33%	11,818	24%
Noven Therapeutics						
Product revenues	24,474		9,213			
Cost of products sold	8,038		3,146			
Gross profit	16,436	67%	6,067	66%		
Total Company						
Product revenues	77,627		65,436		48,326	
Cost of products sold	51,861		41,017		36,508	
Gross profit	$ 25,766	33%	$ 24,419	37%	$ 11,818	24%

In general, Noven Therapeutics products have higher gross margins than our transdermal products because we sell Noven Therapeutics products directly to trade customers at wholesale and commercial prices. Our sales of HT products to Novogyne for resale in the United States have a higher gross margin than our other transdermal products, reflecting favorable pricing, larger production orders and other factors. Our sales of HT products to Novartis Pharma for resale in international markets generally have lower gross margins than sales of HT products sold to Novogyne due to, among other things, unfavorable pricing environments in foreign markets, and smaller production orders. Our gross margin on product sales of Daytrana® to Shire has been negatively affected by the factors described below.

As noted in the tables above, Overall Gross Margin declined in 2008 compared to 2007. Overall Gross Margin in 2008 was negatively affected by: (i) inventory write-offs of $2.8 million, primarily related to an equipment failure

in transdermal manufacturing (comprised of $1.8 million of write-offs of products manufactured for Novogyne and $1.0 million of third party HT product write-offs), as well as additional manufacturing costs incurred in 2008 to address this issue; (ii) cost of products sold in 2008, which included $1.1 million of the 2008 Daytrana® Charges; (iii) inventory write-offs of approximately $1.5 million related to Daytrana® product; (iv) the addition of approximately

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$5.1 million in manufacturing costs in our Noven Transdermals segment over 2007, primarily in the quality assurance area, of which approximately $1.4 million related to costs associated with the Daytrana® peel force issue; and (v) significantly lower product revenues in our Noven Transdermals segment, primarily related to the timing of shipments and delays in the release of Daytrana® product in 2008. Overall Gross Margin in 2008 benefited from the addition of our Stavzor®, Pexeva® and Lithobid® products, which collectively had net sales of $24.5 million and related cost of products sold of $8.0 million, resulting in a gross margin of 67% for those products and a decrease in product inventory at Novogyne which resulted in approximately $0.4 million of recognized deferred profit on product sold to Novogyne.

As noted in the tables above, Overall Gross Margin improved significantly in 2007 compared to 2006. Overall Gross Margin in 2007 benefited from: (i) the addition of our Pexeva® and Lithobid® products, which had net sales of $9.2 million and related cost of products sold of $3.1 million, resulting in a gross margin of 66% for those products; (ii) significantly higher product revenues due to full-year sales of Daytrana®; higher facility utilization for our transdermal products, which contributed to improved overhead absorption; cost savings associated with our cost reduction program initiated in the third quarter of 2006; and (iii) a $1.3 million increase in price reconciliation payments relating to international sales of our HT products for 2007 as compared to 2006, which payments increase product revenues without increasing costs.

We sell Daytrana® finished product to Shire at a fixed cost, and consequently, our profit on product sales of Daytrana® depends on our ability to manufacture the product efficiently and to fully utilize our facilities. For 2008, Daytrana® net product revenues were $10.8 million and cost of products sold related to Daytrana® was $17.8 million, resulting in negative gross margin for the product. This compares with Daytrana® product revenues of $13.4 million and cost of products sold related to Daytrana® of $14.8 million for 2007. Daytrana® gross margin was negatively affected in 2008 by the 2008 Daytrana® Charges as well as increased manufacturing and quality assurance related expenditures, including, as discussed above, approximately $1.4 million related to costs associated with the Daytrana® peel force issue. Although we have implemented new manufacturing processes that helped improve efficiencies associated with existing Daytrana® production in the fourth quarter of 2008, we expect the peel force issue to continue to negatively affect margins as a result of increased Daytrana® manufacturing costs, including reimbursements to Shire for the AMI included in destroyed product, unless and until the peel force issue is resolved.

We expect to continue to incur increased quality assurance costs related to our continued efforts to improve our quality assurance systems and to address the issues raised by the FDA and a significant portion of these continuing costs will be allocated to Daytrana®, which we expect to negatively affect the gross margin on sales of this product in 2009 and beyond.

Our expectations for gross margins in future periods are addressed under Outlook below.

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Operating Expenses:

Operating expenses are summarized as follows (dollar amounts in thousands):

	Years Ended December 31,				
	2008	% Change	2007	% Change	2006
Research and development	$15,527	11%	$ 13,978	22%	$11,454
Acquired in-process research and development		N/M	100,150	N/M	
Selling and marketing	23,299	154%	9,160	847%	967
General and administrative	36,796	21%	30,411	47%	20,734

N/M Not Meaningful

Research and Development

Research and development expenses include costs associated with, among other things, product formulation, pre-clinical testing, clinical studies, regulatory and medical affairs, production for clinical and regulatory purposes, production related development engineering for developmental products, and the personnel associated with each of these functions.

The $1.5 million increase in research and development expenses for 2008 compared to 2007 was attributable to a $2.0 million increase in clinical research and development, primarily for Mesafem , partially offset by a $0.5 million decrease in clinical research costs for other developmental products.

The $2.5 million increase in research and development expenses for 2007 compared to 2006 was primarily due to a $1.9 million increase in clinical research costs on transdermal developmental products and $1.5 million in expenses as a result of the acquisition of Noven Therapeutics. These increases in 2007 were partially offset by a $1.0 million decline in development engineering expenses primarily related to Daytrana® prior to the product s launch in the second quarter of 2006.

Acquired In-Process Research and Development

Immediately following the closing of the Noven Therapeutics acquisition, we expensed $100.2 million in 2007 representing the portion of the purchase price allocated to in-process research and development in our acquisition of Noven Therapeutics. This amount represents the value assigned to projects that have been initiated and achieved material progress but (i) have not yet reached technological feasibility or have not yet reached the appropriate regulatory approval; (ii) have no alternative future use; and (iii) the fair value is estimable with reasonable certainty.

Selling and Marketing

The $14.1 million increase in selling and marketing costs for 2008 compared to 2007 were attributable to the addition of Noven Therapeutics in August 2007, which added $14.5 million of selling and marketing costs in 2008, including $4.8 million related to Stavzor®, which was launched in August 2008.

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The $8.2 million increase in selling and marketing costs for 2007 compared to 2006 were primarily attributable to the addition of Noven Therapeutics in August 2007, related to the sales and marketing of Pexeva® and Lithobid®.

General and Administrative

General and administrative expenses increased $6.4 million, or 21%, for 2008 compared to 2007, reflecting $4.8 million of the 2008 Daytrana® Charges (compared to $2.2 million in 2007), a $1.8 million charge related to a patent infringement case, a $1.5 million increase in salary and related benefits primarily as a result of filling key executive positions, a $1.4 million increase in professional fees, primarily attributable audit and accounting fees and executive recruiting, a $0.6 million loss on the disposal of assets, and a $1.8 million increase across other general and administrative expense categories. These increases were partially offset by the absence of a $3.3 million charge recorded in 2007 related to certain executive separations.

General and administrative expenses increased $9.7 million, or 47%, for 2007 compared to 2006. The increase was attributable to a $3.9 million increase in compensation expenses, of which $3.3 million related to separation arrangements with certain executive officers. Also contributing to the increase was $2.2 million in costs associated with Shire s 2007 voluntary recalls of Daytrana®, a $2.1 million increase as a result of the addition of Noven Therapeutics and a $1.6 million increase in professional fees.

Reversal of Contingent Milestone Liability

In 2008, we recognized $5.0 million in operating income as a result of the reversal of an accrued liability for the final contingent milestone payment to Synthon upon a determination that the achievement of the final sales milestone for annual net sales of Pexeva® was no longer probable.

Other Income and Expenses

Interest and Other Income

Interest and other income decreased $3.4 million, or 63%, in 2008 compared to 2007. This decrease was primarily attributable to a decrease in cash available for investment as a result of the payment of $130.4 million in connection with the Noven Therapeutics acquisition in August 2007, as well as additional sales of auction rate securities at par during 2008 and lower interest rates on our remaining investments.

Interest and other income increased $1.2 million, or 28%, in 2007 compared to 2006. This increase was primarily attributable to an increase in cash available for investment due to our receipt from Shire of sales milestone payments of $25.0 million in March 2007 and $25.0 million in August 2007. These cash increases were offset by the $130.4 million in cash consideration related to the Noven Therapeutics acquisition, which decreased our cash available for investment in the third and fourth quarter of 2007.

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Income Taxes

Our effective tax rate was approximately 35% for 2008 and 2007 and 33% for 2006. The provision for income taxes is based on the Federal statutory and state income tax rates. Net deferred income tax assets are measured using the average graduated tax rate for the estimated amount of annual taxable income in the years that the liability is expected to be settled or the asset recovered. The effect of adjusting the expected tax rate related to the net deferred income tax assets is included in the provision for income taxes. The acquisition of Noven Therapeutics resulted in a significant increase in our deferred income tax assets, primarily due to the $100.2 million of acquired in-process research and development which was expensed immediately under GAAP, but is being deducted over 15 years for tax purposes. As of December 31, 2008 we had a net deferred tax asset of $72.2 million compared to $65.7 million at December 31, 2007. Realization of this deferred tax asset depends upon the generation of sufficient future taxable income. A valuation allowance is established if it is more likely than not that all or a portion of the deferred tax asset will not be realized. Noven Therapeutics files separate state income tax returns in states where it has determined that it is required to file state income taxes. As a result, state deferred tax assets relating to Noven Therapeutics are evaluated separately in determining whether the state deferred tax assets are realizable. Noven Therapeutics has historically reported taxable losses in these states and we expect that Noven Therapeutics will continue to incur state taxable losses in the next few years. These circumstances create negative evidence indicating the need for a valuation allowance at December 31, 2008. Our valuation allowance for state deferred tax assets was $3.5 million and $3.2 million as of December 31, 2008 and 2007, respectively, due to uncertainty about our ability to realize these state deferred tax assets based on our projection of future state taxable income. If we determine, based on future profitability of Noven Therapeutics that these state deferred tax assets will more likely than not be realized, a release of all, or part, of the related valuation allowance could result in an immediate income tax benefit in the period the valuation allowance is released.

The increase in our effective tax rate for 2007 as compared to 2006 related primarily to a higher percentage of our income that was subject to state income taxes and lower tax-exempt interest income as a percentage of our total loss due to the sale of investments to fund the Noven Therapeutics acquisition.

Equity in Earnings of Novogyne

We share in the earnings of Novogyne according to an established formula after satisfaction of an annual preferred return of $6.1 million to Novartis. Our share of Novogyne s earnings (a non-cash item) increases as Novogyne s earnings increase, subject to a cap of 49%. Novogyne earned sufficient income in each of 2008, 2007 and 2006 to meet Novartis annual preferred return for those periods and for us to recognize earnings from Novogyne under the formula. We report our share of Novogyne s earnings as Equity in earnings of Novogyne in our Consolidated Statements of Operations.

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Novogyne records revenues net of sales allowances for rebates, chargebacks, cash and other discounts and sales returns allowances. The financial results of Novogyne are summarized as follows (dollar amounts in thousands):

	Years Ended December 31,				
	2008	% Change	2007	% Change	2006
Gross revenues	$ 197,994	16%	$ 171,347	11%	$ 154,901
Sales allowances	23,731	8%	21,912	27%	17,226
Sales returns allowances	4,645	221%	1,447	-75%	5,732
Sales and returns allowances	28,376	21%	23,359	2%	22,958
Net revenues	169,618	15%	147,988	12%	131,943
Cost of sales	33,795	8%	31,203	3%	30,149
Gross profit	135,823	16%	116,785	15%	101,794
Gross margin percentage	80%		79%		77%
Selling, general and administrative expenses	37,471	-2%	38,084	2%	37,319
Income from operations	98,352	25%	78,701	22%	64,475
Interest income and other	1,129	-1%	1,145	36%	842
Net income	$ 99,481	25%	$ 79,846	22%	$ 65,317
Noven s equity in earnings of Novogyne	$ 45,642	27%	$ 35,850	25%	$ 28,632

Novogyne Net Revenues

Novogyne sells its products to trade customers, including wholesalers, distributors and chain pharmacies. As has historically been the case, the timing of purchases by trade customers is driven by the inventory needs of each customer and other factors, and does not necessarily track underlying prescription trends in any given period or coincide with Novogyne s quarterly financial reporting periods. As a result, the timing of orders by trade customers is difficult to predict and can lead to significant variability in Novogyne s quarterly results.

Novogyne s gross revenues increased $26.6 million for 2008 compared to 2007. By product, Vivelle-Dot® and CombiPatch® increased $30.9 million and $1.0 million, respectively, while Vivelle® (a discontinued product) decreased $5.4 million. The $30.9 million Vivelle-Dot® increase consisted of a $19.0 million increase related to pricing and an $11.9 million increase in unit sales, which is consistent with increases in prescription trends. The $1.0 million CombiPatch® increase was attributable to a $1.5 million increase related to pricing, partially offset by a $0.5 million decline in unit sales which resulted from a continued decline in the market for combination therapies, and the impact of a competitive product.

Novogyne s gross revenues increased $16.4 million for 2007 compared to 2006. By product, Vivelle-Dot® increased $17.9 million while Estradot®, Vivelle® and CombiPatch® declined $0.8 million, $0.6 million and $0.1 million, respectively. The $17.9 million Vivelle-Dot® increase consisted of an $11.3 million increase related to pricing and a $6.6 million increase from higher unit sales due to increased product demand and to the timing of orders. The decline in Estradot® was attributable to the timing of orders. The decline in Vivelle®, the first

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generation estrogen patch, is attributable to a $1.0 million decline due to lower unit sales resulting from product maturity and the continuing market transition to Vivelle-Dot®, partially offset by a $0.4 million increase related to pricing. The decline in CombiPatch® results from a $1.4 million decrease due to lower unit sales as the market for combination therapies continues to decline, and the impact of a competitive product. The CombiPatch® decline was partially offset by a $1.3 million increase related to an increase in the pricing of the product.

Sales allowances consist of chargebacks, Medicaid rebates, managed healthcare rebates, cash discounts and other allowances, which tend to fluctuate based on changes in gross revenues. For 2008, 2007 and 2006, these sales allowances were 12%, 13% and 11%, respectively, of gross revenues.

The following table describes Novogyne s sales and returns allowances (dollar amounts in thousands):

	Years Ended December 31,					
	2008	% of gross revenues	2007	% of gross revenues	2006	% of gross revenues
Gross revenues	$ 197,994	100%	$ 171,347	100%	$ 154,901	100%
Managed health care rebates	14,578	7%	13,226	8%	10,117	7%
Cash discounts	3,920	2%	3,387	2%	3,042	2%
Medicaid, Medicare & State program rebates and credits including prescription drug saving cards	1,340	1%	1,637	1%	981	1%
Chargebacks, including hospital chargebacks	1,423	1%	1,298	1%	1,032	1%
Other discounts	2,470	1%	2,364	1%	2,054	1%
Sales allowances	23,731	12%	21,912	13%	17,226	11%
Sales returns allowances	4,645	2%	1,447	1%	5,732	4%
Sales and returns allowances	28,376	14%	23,359	14%	22,958	15%
Net revenues	$ 169,618	86%	$ 147,988	86%	$ 131,943	85%

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Sales returns allowances consist of allowances for returns of expiring product. The activity in the sales returns allowances was as follows (amounts in thousands):

	Years Ended December 31,		
	2008	2007	2006
Sales returns allowances included in net revenues	$ 4,645	$ 1,447	$ 5,732
Actual returns primarily for expiring product	(3,466)	(3,349)	(3,962)
Change in allowances for returns primarily for expiring product	$ 1,179	$ (1,902)	$ 1,770

The increase in sales returns allowances for 2008 compared to 2007 is primarily attributable to an increase in sales of Vivelle-Dot® as well as a revision to the return rate for Vivelle-Dot® in the current period due to an increase in the rate of actual returns for the product. In addition, 2007 benefited from a reduction in allowances for expiring product due to lower than expected returns as a result of a decline in actual returns of CombiPatch® at the time.

The decrease in sales returns allowances as a percentage of gross revenues for 2007 compared to 2006 was primarily related to lower actual returns of CombiPatch® in 2007. The higher returns of CombiPatch® in 2006 compared to 2007 primarily related to returns of a superseded packaging configuration.

Novogyne Gross Margin

The increase in gross margin percentage for 2008 as compared to 2007 was primarily related to higher sales of Vivelle-Dot®, which has a higher gross margin than the other products sold by Novogyne, as well as price increases for all products, partially offset by higher sales returns allowances due to the increase in such allowances for Vivelle-Dot®.

The two percentage point gross margin increase for 2007 as compared to 2006 was primarily related to higher pricing, especially for Vivelle-Dot®, and to an aggregate decrease in sales returns allowances due to lower returns of CombiPatch®.

Novogyne Selling, General and Administrative

Novogyne s selling, general and administrative expenses decreased $0.6 million for 2008 compared to 2007 primarily due to a $0.8 million decrease in sample expenses due to the timing of shipments by Noven to Novogyne and an aggregate $0.2 million decrease in marketing, advertising and promotional expenses attributable to product marketing efficiency efforts. These decreases were partially offset by a $0.4 million increase in HT litigation expenses.

Novogyne s selling, general and administrative expenses increased $0.8 million for 2007 compared to 2006 due to a $1.2 million increase in sample expenses and a $0.5 million increase in sales, marketing and advertising expenses. These increases were partially offset by a $0.9 million decline in HT litigation expenses.

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Liquidity and Capital Resources

As of December 31, 2008 and December 31, 2007, Noven had the following (amounts in thousands):

	December 31,	
	2008	2007
Cash and cash equivalents	$62,875	$13,973
Short-term investments	3,650	21,565
Working capital	50,644	24,024

In addition to our cash and working capital, as of December 31, 2008, we owned investments in auction rate securities with a fair value of $15.5 million, of which $3.7 million has been called by the issuer and is included in current assets. Due to the current illiquid market conditions and failed auctions, we have classified the remaining $11.8 million of these investments as non-current assets; however, these investments have been a source of liquidity during 2008, including proceeds of $39.0 million from sales and redemptions of these auction rate securities at par during 2008. On a combined basis, our cash and cash equivalents and investments in auction rate securities were as follows (amounts in thousands):

	December 31,	
	2008	2007
Cash and cash equivalents	$ 62,875	$ 13,973
Investments in auction rate securities:		
Current	3,650	21,565
Non-current	11,810	32,835
Total cash and cash equivalents and investments	$ 78,335	$ 68,373

Cash provided by (used in) operating, investing and financing activities is summarized as follows (amounts in thousands):

	Years Ended December 31,		
	2008	2007	2006
Cash flows:			
Operating activities	$ 19,597	$ 54,369	$ 60,027
Investing activities	32,273	(43,499)	(133,511)
Financing activities	(2,968)	(6,041)	15,664
Net cash flows	$ 48,902	$ 4,829	$ (57,820)

Operating Activities

Net cash provided by operating activities for 2008 primarily resulted from the receipt of $42.0 million in distributions from Novogyne and a $25.0 million milestone payment from Shire. Significant operating cash outflows during 2008 included income tax payments of $20.8 million, $5.4 million of employee severance, bonus and retention payments, payments to Shire of $3.7 million and $3.3 million related

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to its 2008 and 2007 voluntary recalls of certain Daytrana® product, respectively, and $3.5 million in payments related to insurance premiums. In addition, changes in working capital, including a $6.8 million increase in inventories and a $1.8 million decrease in accrued compensation and related liabilities, also partially offset the net cash provided by operating activities.

Net cash provided by operating activities for 2007 primarily resulted from the receipt of $50.0 million in milestone payments from Shire, our receipt of $28.8 million in cash distributions from Novogyne, and our receipt of $5.9 million in connection with the amphetamine transdermal system collaborative agreement with Shire. These amounts were partially offset by changes in working capital due to the timing of certain payments, including $23.7 million in tax payments, $3.0 million in insurance payments and an increase of $3.1 million in compensation and related liabilities.

Net cash provided by operating activities in 2006 primarily resulted from the receipt of $50.0 million from Shire related to the final marketing approval of Daytrana® by the FDA and $26.4 million in cash distributions from Novogyne. These receipts were offset by changes in working capital due to the timing of certain payments, including reimbursement payments of $5.1 million to Shire for clinical trial costs incurred in connection with obtaining Daytrana® regulatory approval, $3.9 million for compensation and related liabilities and $2.6 million related to insurance.

Investing Activities

Noven has invested a portion of its cash in investments, which primarily consist of investment grade, auction rate securities, which are categorized as available-for-sale under the provisions of SFAS No. 115 Accounting for Certain Investments in Debt and Equity Securities .

Net cash provided by investing activities for 2008 was primarily attributable to $39.0 million in sales of investments at par, partially offset by $3.8 million in equipment purchases to support operations and a $1.5 million milestone payment to Banner upon approval of Stavzor® in the third quarter of 2008.

Net cash used in investing activities for 2007 was primarily attributable to $130.4 million in acquisition costs related to the acquisition of Noven Therapeutics, net of cash acquired, and $2.8 million in equipment purchases to support operations and expansion of facilities, partially offset by $90.1 million of proceeds from the sale of short-term investments primarily used to fund the Noven Therapeutics acquisition.

Net cash used in investing activities in 2006 was primarily attributable to $126.4 million in net purchases of short-term investments, as well as the purchase of $6.3 million in fixed assets to expand production capacity for future products. Beginning in the first quarter of 2005, Noven invested a portion of its cash in short-term investments, which primarily consist of investment grade, asset backed, variable rate debt obligations and municipal auction rate securities, which are categorized as available-for-sale under the provisions of SFAS No. 115.

Financing Activities

Net cash used in financing activities for 2008 was primarily attributable to a $3.3 million sales milestone payment to Synthon, an obligation assumed as part of the Noven Therapeutics acquisition.

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Net cash used in financing activities for 2007 was primarily attributable to the open-market purchase of $5.1 million of our common stock under the stock repurchase program established in the third quarter of 2007 and the payment of a $3.7 million long-term obligation assumed as part of the acquisition of Noven Therapeutics. These payments were offset by $2.5 million received as the exercise price paid by option holders in connection with the exercise of stock options. In addition, 2007 benefited from $0.4 million in excess tax benefit from the exercise of stock options.

Net cash provided by financing activities in 2006 was attributable to $13.2 million received as the exercise price paid by the option holders in connection with the exercise of stock options. In addition, 2006 benefited from $2.6 million in excess tax benefit from the exercise of stock options, which prior to the adoption of SFAS No. 123(R) was reported in operating activities.

Short-Term and Long-Term Liquidity

Our principal sources of short-term liquidity are existing cash and distributions from Novogyne. Additional sources of short-term liquidity include cash generated from product sales, license fees and royalties under development and license agreements.

Our short-term cash flow is significantly dependent on distributions from Novogyne and sales, royalties and license fees associated with our products. Any material decrease in sales of those products by us or our licensees, a material decline in the HT market, the introduction of a generic version of Vivelle-Dot®, material increases in operating expenses, or the inability or failure of Novogyne to pay distributions, would have a material adverse effect on our short-term cash flow and require us to rely on our existing cash balances, investments, equity or debt offerings or on borrowings to support our operations and business.

During 2008, our cash and cash equivalents and investments in auction rate securities increased from $68.4 million to $78.3 million. The increase primarily resulted from the receipt of the third and final $25.0 million sales milestone payment from Shire and $42.0 million of distributions from Novogyne. The cash increases were partially offset by certain cash outlays in 2008, including (i) $20.8 million of income tax payments in 2008; (ii) $3.8 million for equipment purchases; (iii) $3.7 million of payments to Shire for Shire s voluntary withdrawals of Daytrana® product in 2008; (iv) $3.5 million for insurance premiums; (v) a $1.5 million milestone payment in connection with market approval for Stavzor®; and (vi) cash used to fund increases in inventory and other working capital items. In addition, we also paid certain obligations previously charged to operations in 2007 and/or accrued as of December 31, 2007, including (i) $5.4 million of employee severance, bonus and retention payments; (ii) $3.3 million of costs associated with Shire s 2007 voluntary withdrawals of Daytrana® product; and (iii) a $3.3 million milestone payment related to Noven Therapeutics products. We believe that our existing cash balances and expected collections of receivables, together with the available capacity under our credit facility (described below), will be sufficient to meet our operating needs and short-term capital requirements.

We received the first $25.0 million sales milestone payment from Shire relating to its sales of Daytrana® in the first quarter of 2007, the second $25.0 million Daytrana® sales milestone payment in the third quarter of 2007 and the third $25.0 million Daytrana® sales milestone payment in the third quarter of 2008. We paid an aggregate $20.8 million and $23.7 million in taxes during 2008 and 2007, respectively, of which approximately $8.8 million and $18.0 million relates to Daytrana® milestones received to date. We expect to pay income taxes related to the final Daytrana® milestone payment of approximately $8.5 million during 2009.

As discussed elsewhere herein, we paid Shire $3.7 million related to Shire s voluntary recalls of Daytrana® product in 2008. In addition, we reserved $3.8 million in 2008 for certain previously-manufactured Daytrana® lots that would not meet the new release testing standard and

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are probable of being voluntarily withdrawn or recalled from the market prior to expiration of their shelf life, and which therefore would require additional reimbursements to Shire.

In April 2008, we made a $3.3 million milestone payment to Synthon based on achieving specified net sales of Pexeva® during 2007. We expect to pay an additional $3.3 million milestone to Synthon in 2009 based on 2008 net sales of Pexeva®.

We have invested a significant portion of our cash in auction rate securities, which subjects us to the liquidity risk described in Part II Item 7A Quantitative and Qualitative Disclosures About Market Risk . During 2008, we recorded $0.5 million of other-than-temporary impairments on our investments in auction rate securities which are classified as available-for-sale under SFAS No. 115. As of December 31, 2008, the total par value and fair value of our investments in auction rate securities was $16.0 million and $15.5 million, respectively. We liquidated $39.0 million of our investments in auction rate securities at par value during 2008. An additional $3.7 million has been called by the issuer and is expected to be redeemed in March 2009. Due to continuing auction failures beginning in February 2008, we utilized valuation models to determine the fair values of our investments in auction rate securities. The fair values of our investments were calculated based on the following: (i) the underlying structure of each security; (ii) the present value of future principal and interest payments discounted at rates considered to reflect current market conditions; (iii) consideration of the probabilities of default, auction failure, or repurchase at par for each period; and (iv) consideration of third party credit enhancement. These estimated fair values could change significantly based on future market conditions.

Changes to investments measured at fair value on a recurring basis using unobservable inputs (Level 3) during 2008 were as follows (amounts in thousands):

Balance at December 31, 2007	$ 54,400
Purchases of investments	550
Sales of investments at par	(38,975)
Unrealized losses, other-than-temporary	(515)
Balance at December 31, 2008	$ 15,460

As a result of failed auctions, our auction rate securities pay interest at rates as defined by the governing documents or indenture. Due to uncertainty regarding the timing of our future investment liquidations, we have classified our auction rate securities as non-current assets as of December 31, 2008, except for the called security, which is included in current assets. As illiquid conditions persist in the auction market for these securities, it may become increasingly more likely that we will need to recognize additional other-than-temporary impairment charges in future periods. Such non-cash impairment charges could materially and adversely affect our consolidated financial condition and results of operations.

We paid approximately $125.0 million in cash to acquire Noven Therapeutics in August 2007 and incurred approximately $5.4 million in transaction-related costs. We funded the purchase price and related transaction expenses from our sale of short-term investments. In addition, we assumed approximately $16.1 million of accrued expenses and other current liabilities and assumed certain contractual arrangements under which we may be required to pay to third parties up to $8.3 million in product development and sales milestones as of December 31, 2008. See Note 19 Commitments and Contingencies Noven Therapeutics Commitments in the Notes to our Consolidated Financial Statements for further information.

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During 2008, proceeds from stock option exercises were not significant. We expect the amount of proceeds from stock option exercises to fluctuate from period to period depending on the price of our common stock and equity award exercises. Beginning in 2006, we began granting SSARs to employees and restricted stock to non-employee directors in lieu of stock options. These types of awards do not provide us with cash upon their exercise. Accordingly, we expect that funds received from option exercises will become less of a source of funds over time.

In July 2008, we entered into an agreement for a $15.0 million credit facility. In connection with the credit facility and in lieu of granting a security interest in our assets, we agreed not to pledge, grant any security interest in, or allow any lien or encumbrance in or on, certain of our financial assets. The facility expires in July 2009. As of the date of this report, no borrowings were outstanding under this facility and we have no long-term debt. To the extent the sources of liquidity described above are insufficient to fund our operations, we would expect to seek to obtain funds through debt and/or equity financing. We cannot provide any assurance that such financing will be available, if at all, in a timely manner, or on favorable terms. If we are unable to obtain satisfactory financing, we may be required to delay or reduce our proposed expenditures, plant and equipment and strategic acquisitions. Furthermore, debt financing would likely require us to devote funds to service and ultimately repay such debt and could subject us to financial or operational covenants that could limit or hinder our ability to conduct our business.

Our strategic plan includes the acquisition of one or more products, technologies or businesses that we believe may be complementary to our business. We expect that we will be required to seek debt and/or equity financing to complete such an acquisition. Current conditions in the credit markets and equity markets could make it particularly difficult to raise funds on attractive terms, if at all. We cannot provide any assurance that such financing will be available, if at all, in a timely manner, or on favorable terms.

Capital expenditures totaled $3.8 million for 2008. We expect to fund our foreseeable capital expenditures from our operating cash flows, existing cash, short-term investments and debt.

If our transdermal products under development are successful, we may need to fund plant and equipment purchases to expand production capacity. For our long-term operating needs, we intend to utilize funds derived from the sources described above. To the extent available, we may use funds generated through sales of products under development and payments received pursuant to development and licensing arrangements. If such funds are insufficient, we may rely on debt and/or equity financing to fund such expansion. We cannot assure that we will successfully complete the development of such products, that we will obtain regulatory approval for any such products, that any approved product will be produced in commercial quantities, at reasonable costs, and be successfully marketed, or that we will successfully negotiate future licensing or product acquisition arrangements. Because much of the cost associated with product development and expansion of manufacturing facilities is incurred prior to product launch, if we are unsuccessful in out-licensing, or if we are unable to launch additional commercially-viable products that we develop or that we license or acquire from others, we will have incurred the up-front costs associated with product development or acquisition without the benefit of the cash generated by sales of those products, which could adversely affect our long-term liquidity needs. Factors that could impact our ability to develop or acquire and launch additional commercially-viable products are discussed in Part I Item 1A Risk Factors of this Form 10-K.

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For the years ended December 31, 2008, 2007 and 2006, our equity in earnings of Novogyne and the recognition of deferred license and contract revenues (both of which are non-cash items) contributed significantly to our income before income taxes. Accordingly, our net income may not be reflective of our cash flow in any given period.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements.

Aggregate Contractual Obligations

The table below lists our significant contractual obligations as of December 31, 2008 (amounts in thousands):

	Total	Less Than 1 year	1 - 3 years	3 - 5 years	More than 5 years
Operating Lease Obligations[1]	$ 6,560	$ 1,407	$ 2,294	$ 1,968	$ 891
Capital Lease Obligation[2]	188	155	16	16	1
Deferred Compensation Obligation	515	139	195	67	114
Long-Term Obligations[3]	3,250	3,250			
Purchase Obligations[4]	26,293	26,289	4		
Unrecognized Tax Benefits	1,343	302	236	565	240
Total	$ 38,149	$ 31,542	$ 2,745	$ 2,616	$ 1,246

[1] In the ordinary course of business, we enter into operating leases for machinery, equipment, warehouse and office space. Total lease expense for operating leases was $2.1 million, $1.5 million and $1.2 million for the years ended December 31, 2008, 2007 and 2006, respectively.

[2] Noven did not enter into capital lease obligations in

2008. During 2007 and 2006, Noven entered into capital lease obligations for new equipment totaling $0.1 million and $0.4 million, respectively, of which $0.2 million (including interest) remains outstanding as of December 31, 2008.

[3] Represents $3.3 million sales milestone payable in 2009 based on 2008 sales of Pexeva®.

[4] In the ordinary course of business, we enter into non-cancelable purchase obligations to vendors to which we have submitted purchase orders, but have not yet received the goods or services.

Outlook

A summary of our current financial guidance is provided below. This financial guidance supersedes all financial guidance that we may have previously provided. Any financial guidance previously provided in areas not addressed below, whether in prior filings with the Securities and Exchange Commission, press releases, public conference calls or otherwise, is no longer current and is hereby withdrawn. The forward-looking information contained in this section is based on our current assumptions and expectations, many of which are based upon matters beyond our control. In particular, for purposes of this guidance we have assumed that, during 2009, there will not be any material:

acquisitions of products, companies, or technologies or other transactions;

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changes in Noven s or Novogyne s accounting or accounting principles or any of the estimates or judgments underlying our critical accounting policies;

regulatory or technological developments;

changes in the supply of, demand for, or distribution of our products (including any changes resulting from competitive products, unexpected product recalls/withdrawals, or new study results);

negative actions with respect to our applications for methylphenidate quota or other disruptions in supplies of raw materials;

adverse actions by the FDA in connection with the January 2008 warning letter or otherwise;

changes in our business relationships/collaborations; or

changes in the economy, health care reimbursement policies or the health care sector generally.

Financial guidance is inherently uncertain. Accordingly, we cannot assure that we will achieve results consistent with this guidance, and our actual financial results could differ materially from the expected results discussed below. For a discussion of certain factors that may impact our actual financial results for the periods referenced, including additional risks and uncertainties related to Noven Therapeutics, readers should carefully consider the risks, uncertainties and cautionary factors discussed in Part I Item 1A Risk Factors of this Form 10-K, as well as other information contained in this Form 10-K and in other reports filed from time to time with the Securities and Exchange Commission.

Net revenues, gross margin, expenses, net income and other aspects of our financial results can vary substantially from quarter-to-quarter based upon a number of factors, including the timing of product orders by our licensees, the timing of release of manufactured product following quality control and quality assurance measures undertaken by Noven and/or its customers, the availability of raw materials, the timing of commencement of clinical studies, and other factors.

Net Revenues. We expect total net revenues for full year 2009 to be in the range of $110 million to $115 million, including license and contract revenues of approximately $26 million.

Gross Margin. We expect our overall gross margin, as a percentage of total net product revenues, to be in the range of 38% to 42% for full year 2009, with a higher gross margin expected in the second half of 2009 than in the first half, reflecting our belief that our gross margin on Daytrana® should improve following commercial production of Daytrana® product incorporating a solution to the peel force issue. If, however, we are unsuccessful in addressing the peel force issue on our expected timeline, our overall gross margin for 2009 would be lower than our forecast range.

Research and Development Expense. We expect our consolidated research and development expense for full year 2009 to be in the low-to-mid $20 million range, reflecting (among other clinical projects) the cost of our ongoing Phase 2 study for Mesafem . Estimates of research and development expenses for future periods are subject to substantial adjustment as each product advances through various stages of development.

Selling, General and Administrative Expense. We expect our consolidated selling, general and administrative expense for full year 2009 to be in the mid $50 million range.

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Noven Therapeutics. We expect to improve the pre-tax contribution from our Noven Therapeutics segment by approximately $5.0 million in full year 2009 compared to 2008 levels.

Equity in Earnings of Novogyne. We expect our equity in earnings of Novogyne to be in the low-to-mid $50 million range for full year 2009.

Earnings Per Share. For full year 2009, we expect to report diluted earnings per share in the range of $0.85 to $0.95 per share.

Cash. We expect to use approximately $5 million to $10 million of cash in 2009 as we continue to invest in Mesafem™ and other programs intended to drive longer-term growth.

Critical Accounting Estimates

Our discussion and analysis of our consolidated financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to revenue recognition as well as estimates related to product returns and sales allowances, the fair value of stock-based compensation granted to employees and outside directors, as well as the net realizable value of our inventories and our deferred tax asset and our effective tax rate and the recoverability and fair value of our intangible assets and goodwill. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Many of our critical accounting estimates are those which we believe require the most subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain or which involve factors that may be beyond our control. Using different assumptions could result in materially different results. A discussion of our critical accounting estimates, the underlying judgments and uncertainties affecting their application and the likelihood that materially different amounts would be reported under different conditions or using different assumptions, is as follows:

License Revenues, Multiple Element Arrangements and Contract Revenues

License revenues consist of the recognition of non-refundable up-front, milestone and similar payments under license agreements. These agreements may contain multiple deliverables, such as product development, technology licenses, contract research and development, and the manufacturing and supply of products.

We recognize license revenue in accordance with the SEC s Staff Accounting Bulletin Topic 13, Revenue Recognition, and Emerging Issues Task Force (EITF) Issue 00-21, Revenue Arrangements with Multiple Deliverables (EITF Issue 00-21), as applicable. Revenue arrangements with multiple deliverables are divided into separate units of accounting if certain criteria are met, including whether the delivered item has standalone value to the customer, and whether there is objective, reliable evidence of the fair value of the undelivered items. Consideration received is allocated among the separate units of accounting based on their relative fair values or using the residual method, as appropriate, and the applicable revenue recognition criteria are identified and applied to each of the units. If multiple deliverables do not meet the separation criteria of EITF Issue 00-21, they are accounted for as a single unit of accounting and management applies a revenue recognition method that best reflects the economic substance of the transaction. In selecting the appropriate method to apply, management considers the specific facts and circumstances of each transaction, giving particular emphasis to the manner in which the customer receives the benefit of the transaction.

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In general, revenues from non-refundable, up-front license fees received prior to or upon product approval are deferred until the revenue recognition criteria have been satisfied and the customer begins to derive the value and benefits from the use of, or access to, the license. Our obligations generally are completed upon achieving regulatory approval of the licensed products, upon delivery of our development work, or when we have delivered a commercially viable license to our technology. In multiple element arrangements where research and development work does not meet the separation criteria of EITF Issue 00-21 (as has typically been the case for our agreements), our policy is to recognize such revenues over the product s estimated life cycle. Our arrangements generally culminate in the delivery to the licensee of technology licenses to market and sell products we have developed in a licensed territory. Historically, we have applied the guidance of EITF Issue 00-21, and have typically determined that the multiple deliverables should be accounted for as a single unit of accounting. Furthermore, we have concluded that the most appropriate revenue attribution method is to defer license revenues and recognize them over the products estimated life cycles, as the customer derives the value from the use of, or access to, the license. When we are unable to estimate the pattern of the expected economic benefits, the deferred revenues are amortized on a systematic and rational (straight-line) basis over the product s estimated life cycle.

We evaluate the facts and circumstances surrounding achievement of non-refundable sales milestones to ensure that revenue recognition represents the substance of the transaction. Substantive sales milestones are recognized as revenue when achieved based on the substance of the underlying transactions, when we have fulfilled all of our obligations relating to the milestone payments. Non-substantive sales milestones are not recognized immediately as revenue when achieved, but are deferred and recognized as revenues over time in a manner that is consistent with the underlying facts and circumstances.

In determining the estimated life cycles over which to recognize license revenues, we consider the remaining life of proprietary protection and the economic lives of competing products in the specific or similar therapeutic categories. We believe the estimated product life cycle (the estimated economic life) generally ends when prescription trends decline to less than 20% of the product s peak prescriptions, which can be impacted by introductions of competing branded products, generic competition, and/or changes/improvements in forms of treatment therapy.

In the event that we receive a non-refundable payment for a product that does not ultimately receive regulatory approval, the payment is recognized as revenue when all efforts cease, the project has been discontinued and we have no further obligation relating to the product.

Shire Collaboration Daytrana®

In 2003, we entered into a collaboration wherein we entered into a license agreement with Shire to market and sell Daytrana® and entered into a manufacturing and supply agreement under which we agreed to supply product to Shire. We determined that the arrangement included three deliverables: (1) a license; (2) a research and development arrangement; and (3) a manufacturing and supply agreement.

The license and research and development deliverables did not meet the criteria for separation under EITF 00-21; therefore, they were combined and accounted for as a single unit of accounting. We concluded that the manufacturing and supply agreement was at fair value based on our experience with similar arrangements; as a result, we accounted for it separate from the single unit of accounting (license and research and development deliverable). Accordingly, all milestone payments (including the up-front payment, FDA approval payment and subsequent

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sales milestones) were allocated to the single unit of accounting. In accordance with our policy, we began to recognize revenue for the single unit of accounting when the revenue recognition criteria related to all deliverables had been satisfied. Specifically, this occurred upon FDA approval of Daytrana® in April 2006, at which time all of our obligations were satisfied, Shire had a commercially viable license and Shire began realizing the value of the deliverable.

In our collaboration with Shire, we receive multiple payment streams. We recognize revenue as a single unit of accounting using a single attribution model for the license and research and development deliverables, whereby all milestone payments are recognized using the straight-line method over the estimated life cycle of Daytrana® (estimated to be seven years), as Shire derives the value from the use of, or access to, the license.

Contract Revenues

Contract revenues consist of the recognition of contract payments related to research and development projects performed for third parties where we have determined that such projects are separate units of accounting. The work we perform may include feasibility studies to determine if a specific drug can be delivered transdermally, the actual formulation of a specific drug into a transdermal drug delivery system, studies to address the ongoing stability of the drug in a transdermal drug delivery system, and manufacturing of batches of product that can be used in human clinical trials. We receive contract payments for the work we perform in the following forms:

non-refundable up-front payments prior to commencing the work (or certain phases of the work);

additional payments upon completion of additional phases; and

in some cases, success milestone payments based on achievement of specified performance criteria.

We recognize revenue from non-refundable, up-front payments based on the proportional performance method as we perform research and development work. We recognize additional payments received upon completion of additional phases and milestone payments when the specified performance criteria are achieved under the milestone method as long as such milestones are substantive. We record any difference between the amount of the payments received and the amount recognized as deferred license and contract revenues on our Consolidated Balance Sheets until such amount is earned.

Revenue Recognition Novogyne

Revenues at Novogyne are recognized when all the risks and rewards of ownership have transferred to the customer, which occurs at the time of shipment of products. Revenues are reduced at the time of sale to reflect expected returns that are estimated based on historical experience. Additionally, provisions are made at the time of sale for all discounts, rebates and estimated sales allowances based on historical experience updated for changes in facts and circumstances, as appropriate. Such provisions are recorded as a reduction of revenues.

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The following table describes the activity for the revenue deduction accruals by major category for Novogyne (in which we hold a 49% investment and account for using the equity method) for the year ended December 31, 2008 (amounts in thousands):

	January 1, 2008	Payments	Income Statement Charge (Reversal) Adjustments of prior years	Current Year	December 31, 2008
Medicaid, Medicare and State program rebates & credits including prescription drug savings cards	$ 896	$ (1,503)	$ (251)	$ 1,591	$ 733
Managed health care rebates	6,149	(13,088)	(11)	14,589	7,639
Chargebacks, including hospital chargebacks	111	(1,426)		1,423	108
Cash discounts, direct customer discounts & other discounts	1,054	(6,579)		6,390	865
Sales returns allowances	6,036	(3,466)	663	3,982	7,215
Total	$ 14,246	$ (26,062)	$ 401	$ 27,975	$ 16,560

These deductions represent estimates of the related obligations, requiring the use of judgment when estimating the impact of these sales deductions on gross sales for a reporting period. These estimates for revenue deductions are derived utilizing a combination of information received from third parties, including market data, inventory reports from its major wholesale customers, historical information and other analysis.

The following briefly describes the nature of each revenue deduction and how the related accruals are estimated by Novogyne:

The United States Medicaid program is a state-government-administered program that uses state and federal funds to provide assistance to certain vulnerable and needy individuals and families. In 1990, the Medicaid Drug Rebate Program was established to reduce state and federal expenditures for prescription drugs. Under the rebate program, rebates are paid to states based on drugs paid for by those states. Provisions for estimating Medicaid rebates are calculated using a combination of historical experience, product and population growth, price increases, the impact of contracting strategies and specific terms in the individual state agreements. These provisions are then adjusted based upon the established re-filing process with individual states. For Medicaid, the calculation of rebates involves interpretation of relevant regulations, which are subject to challenge or change in interpretative guidance by government authorities. Since Medicaid rebates are typically billed up to six months after the product is dispensed, any rebate adjustments may involve revisions of accruals for several quarters.

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Prior to 2006, the products also participated in prescription drug savings programs that offer savings to patients that are eligible participants under United States Medicare programs. These savings vary based on a patient s current drug coverage and personal income levels. Provisions for the obligations under these programs are based on historical experience, trend analysis and current program terms.

On January 1, 2006, an additional prescription drug benefit was added to the United States Medicare program which funds healthcare benefits to individuals over the age of 65. Individuals that previously had dual Medicaid/Medicare drug benefit eligibility had their Medicaid prescription drug coverage replaced on January 1, 2006, by the new Medicare Part D coverage provided through private prescription drug plans. The change led to a significant shift of plan participants between programs in which products participate. Provisions for Medicare Part D rebates are estimated using a combination of specific terms of individual plan agreements, product and population growth, price increases and the impact of contracting strategies.

Wholesaler chargebacks relate to contractual arrangements with certain indirect customers to sell products at prices that are lower than the list price charged to wholesalers. A wholesaler chargeback represents the difference between the invoice price charged to the wholesaler and the indirect customer s contract discount price. Provisions for estimating chargebacks are calculated using a combination of historical experience, product growth rates and the specific terms in each agreement. Wholesaler chargebacks are generally settled within a few weeks of incurring the liability.

Managed health care rebates are offered to key managed health care, group purchasing organizations and other direct and indirect customers to sustain and increase product market share. These rebate programs provide that the customer receive a rebate after attaining certain performance parameters relating to product purchases, formulary status and/or pre-established market share milestones relative to competitors. Since rebates are contractually agreed upon, rebates are estimated based on the specific terms in each agreement, historical experience and product growth rates. The sales performance of products subject to managed health care rebates and other contract discounts and levels of inventory in the distribution channel are tracked, and adjustments to the accrual are made periodically to reflect actual experience.

In order to evaluate adequacy of ending accrual balances, Novogyne uses both internal and external estimates of the level of inventory in the distribution channel and the rebate claims processing lag time. External data sources include periodic reports of wholesalers and purchased third party market data. Management internally estimates the inventory level in the retail channel and in transit.

Novogyne s policy is that no product will be shipped to customers with less than nine months of remaining shelf-life and Novogyne generally will accept returns due to expiration within 12 months after the product has expired. An allowance for estimated sales returns is recorded based on: (i) the historical experience of actual product returns; and (ii) the estimated lag time between when an actual sale takes place in relation to when the products are physically returned by a customer. The historical actual returns rate is then applied to product sales during the estimated lag period to develop the returns estimate. Novogyne also considers trends and expectations for future demand and trade inventory levels. These policies cause a significant lag time between when a product is sold and the latest date on which a return could occur. Novogyne believes this is a reasonable basis on which to estimate returns exposure and incorporates the key factors that contribute to returns. In addition, Novogyne establishes sales returns allowances for product that has been recalled or that it believes is probable of being recalled. The methodology used to estimate product returns associated with recalls is based on the distribution and expiration dates of the affected

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product and overall trade inventory levels. These estimates are based on currently available information, and the ultimate outcome may be different than the amounts estimated given the subjective nature and complexities inherent in this area and in the pharmaceutical industry.

Novogyne s product supply policy is to maintain inventories on a consistent level from year to year based on the pattern of consumption. Wholesaler inventory levels are monitored monthly based on gross sales volume, prescription volumes based on third party data and information received from the key wholesalers. Novogyne believes the third party data sources of information are sufficiently reliable; however its accuracy cannot be independently verified.

Cash discounts are offered to customers to encourage prompt payment. Cash discounts, which are typically 2% of gross sales, are accrued at the time of sale.

Other sales discounts, such as consumer coupons and discount cards, are also offered. These discounts are recorded at the time of sale and estimated utilizing historical experience and the specific terms for each program.

Novartis controls and maintains the reserves associated with such sales allowances and returns on behalf of Novogyne and pays all monies owed and issues credits to individual customers as deemed necessary. The contracts that underlie these transactions are maintained by Novartis for its business as a whole and those transactions relating to Novogyne are estimated by Novartis. Based on an analysis of the underlying activity, the amounts recorded by Novogyne represent Novartis best estimate of charges that apply to sales by Novogyne. However, we cannot control Novartis analysis of the underlying activity or its application of that analysis to Novogyne. If Novartis materially changes the assumptions it uses in determining the reserve, Novogyne may be required to record an additional reserve allowance on its financial statements, which would adversely affect Novogyne s operating results during the period in which the determination or reserve were made, and would consequently also reduce the earnings attributable to our investment in Novogyne for that period.

Revenue Recognition Noven Therapeutics

Revenues at Noven Therapeutics are recognized when all the risks and rewards of ownership have transferred to the customer, which occurs at the time of delivery of the product to the customer. Revenues are reduced at the time of sale to reflect expected returns that are estimated based on historical experience. Additionally, provisions are made at the time of sale for all discounts, rebates and estimated sales allowances based on historical experience updated for changes in facts and circumstances, as appropriate. Such provisions are recorded as a reduction of revenue.

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The following table describes the activity for the revenue deduction accruals by major category for the year ended December 31, 2008 (amounts in thousands):

	January 1, 2008	Payments	Income Statement Charges: Current Year	Other Adjustments	December 31, 2008
Medicaid, Medicare and State program rebates & credits including prescription drug savings cards	$ 4,065	$ (8,624)	$ 7,285	$	$ 2,726
Chargebacks, including hospital chargebacks	139	(1,294)	1,315		160
Cash discounts	59	(817)	835		77
Other discounts	770	(2,053)	1,877		594
Sales returns allowances	1,875	(2,015)	3,410	(200) [1]	3,070
Total	$ 6,908	$ (14,803)	$ 14,722	$ (200)	$ 6,627

[1] Represents credits expected to be issued against customer receivable balances related to product returns.

These deductions represent estimates of the related obligations, requiring the use of judgment when estimating the impact of these sales deductions on gross sales for a reporting period. These estimates for revenue deductions are derived utilizing a combination of information received from third parties, including market data, inventory reports from major wholesale customers, historical information and other analysis. Our management believes that it is able to reasonably estimate these sales deductions, except for Stavzor®, for which we do not yet have sufficient sales history to reasonably estimate returns.

The revenue deductions for Noven Therapeutics and how we estimate the related accruals are substantially similar to the revenue deductions at Novogyne, with the following exceptions:

Noven Therapeutics policy is that generally no product will be shipped to customers with less than 12 months of remaining shelf-life and generally returns due to expiration will be accepted within 12 months after the product has expired.

Noven Therapeutics supply policy is to maintain inventories on a consistent level from year to year based on the pattern of consumption. Wholesaler inventory levels are monitored monthly based on gross sales volume, prescription volumes based on third party data and information received from key wholesalers.

Intangible Assets and Goodwill

We account for acquired businesses using the purchase method of accounting which requires that the assets acquired and liabilities assumed be recorded at the date of acquisition at their respective estimated fair values. The cost to acquire a business, including transaction

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costs, is allocated to the underlying net assets of the acquired business based on estimates of their respective fair values. Amounts allocated to acquired in-process research and development are expensed at the date of acquisition. Intangible assets are amortized over the expected life of the asset. Any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

During 2008, we finalized the purchase price allocation for our Noven Therapeutics acquisition, resulting in a $0.3 million net reduction in goodwill.

The judgments made in determining the estimated fair value assigned to each class of assets acquired and liabilities assumed, as well as asset lives and methods used for amortization, can materially impact our results of operations. Fair values and useful lives are determined based on, among other factors, the expected future period of benefit of the asset, the various characteristics of the asset and projected cash flows. This process requires us to make estimates with respect to future sales volumes, pricing, new product launches, anticipated product costs and overall market conditions. Because these estimates influence the values assigned the various assets acquired, these estimates are considered to be critical accounting estimates. In connection with our acquisition of Noven Therapeutics, in addition to the value of acquired tangible assets and assumed liabilities, we ultimately recorded on our balance sheet $39.1 million of identifiable intangible assets, $14.4 million of goodwill, and $11.5 million of liabilities for contingent payments we expected to make related to the achievement of sales milestones for acquired products. Additionally, our cash flow estimates resulted in allocating $100.2 million of the purchase price to IPR&D. In accordance with SFAS No. 141, Business Combinations (SFAS No. 141), which applied to acquisitions prior to January 1, 2009, the value allocated to IPR&D was immediately charged to operations. Our forecast of future cash flows associated with IPR&D required various assumptions to be made including:

- revenues that are likely to result from the approved products or IPR&D projects, including estimated number of units to be sold, estimated selling prices, estimated market penetration, estimated market share, year-over-year growth rates over the product life cycles and estimated sales allowances;
- contract and license revenues generated by approved products or IPR&D projects;
- cost of sales for the potential products using historical data, industry data or other sources of market data;
- sales and marketing expenses using historical data, industry data or other sources of market data;
- general and administrative expenses;
- research and development expenses; and
- future equity in earnings of Novogyne.

Additional information about assumptions and other considerations related to the valuation of IPR&D can be found in the notes to our Consolidated Financial Statements.

Our goodwill is assigned to our Noven Therapeutics reporting segment. Goodwill is tested for impairment annually in the fourth quarter or more frequently, when events or other changes in circumstances indicate that the carrying value of goodwill may not be recoverable. If we determine at the date of the evaluation that the fair value of the reporting segment is less than its carrying value, then we would allocate the fair value of the segment to all of the assets and liabilities of the reporting segment in a manner similar to the allocation of purchase price in a business combination. A goodwill impairment would be recognized to the extent that the carrying value of goodwill exceeds the fair value not allocated to identifiable assets. In accordance with SFAS No. 141, our finite-lived intangible assets are evaluated for impairment whenever

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events or circumstances indicate that the carrying amounts may not be recoverable. We would recognize an impairment to the extent that the carrying value of a finite-lived intangible asset exceeds its fair value.

As of December 31, 2008, we determined that no impairment of goodwill or intangible assets existed. We will continue to assess the carrying value of goodwill and intangible assets in accordance with applicable accounting guidance.

Income Taxes

Our future effective tax rate is based on estimates of expected income and enacted statutory tax rates, as applied to our operations. Significant judgment is required in making these determinations and the ultimate resolution of our tax return positions could differ from current expectations. Despite our belief that our tax return positions are correct, our policy is to establish accruals for tax contingencies that may result from examinations by tax authorities. Our tax accruals are analyzed periodically and adjustments are made as events occur to warrant such adjustment. It is reasonably possible that our effective tax rate and/or cash flows may be materially impacted by the ultimate resolution of our tax positions. If we are assessed interest and/or penalties by governing jurisdictions, we include those amounts in our tax provision. Our effective tax rate was 35% in 2008 and 2007and 33% in 2006. If our effective tax rate differed from our estimate, our results would vary.

Accounting principles generally accepted in the United States require that we record a valuation allowance against our net deferred tax asset if we cannot conclude that we will more likely than not be able to generate sufficient future taxable income to utilize our net deferred tax asset. At December 31, 2008 and December 31, 2007, net deferred tax assets were $72.2 million and $65.7 million, respectively.

Realization of these deferred tax assets depends upon the generation of sufficient future taxable income. Estimates of future taxable income require us to make significant estimates that involve subjective and often complex judgments, the most significant of which relate to future cash flows of approved products and products in IPR&D. A valuation allowance is established if it is more likely than not that all or a portion of the deferred tax asset will not be realized. Noven Therapeutics files separate state income tax returns in states where Noven Therapeutics has determined that it is required to file state income taxes. As a result, state deferred tax assets relating to Noven Therapeutics are evaluated separately in determining whether the state deferred tax assets are realizable. Noven Therapeutics has historically reported taxable losses in these states and we expect that Noven Therapeutics will continue to incur state taxable losses in the next few years. These expected taxable losses create negative evidence indicating the need for a valuation allowance at December 31, 2008 and December 31, 2007. Our valuation allowance for state deferred tax assets was $3.5 million and $3.2 million as of December 31, 2008 and December 31, 2007, respectively, due to uncertainty about our ability to realize these state deferred tax assets based on our projection of future state taxable income relating to Noven Therapeutics. If we determine, based on future Noven Therapeutics profitability that these state deferred tax assets will more likely than not be realized, a release of all, or part, of the related valuation allowance could result in an immediate income tax benefit in the period the valuation allowance is released.

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Stock-Based Compensation

On January 1, 2006, we adopted SFAS No. 123(R), which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees and directors based on estimated fair values. Pre-tax stock-based compensation expense recognized under SFAS No. 123(R) was $4.8 million, $5.4 million and $3.3 million in 2008, 2007 and 2006, respectively.

We use the Black-Scholes option pricing model to determine the fair value of stock options and SSARs. The determination of the fair value of stock-based payment awards on the date of grant using an option-pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include our expected stock price volatility over the term of the awards, actual and projected employee equity award exercise behaviors, risk-free interest rate, expected forfeiture rates and expected dividends.

The expected term of stock options/SSARs is defined as the expected time that options will remain outstanding assuming they are not forfeited prior to the vest date. We estimate the expected term using a statistical predictive model that incorporates Noven s historical exercise activity in conjunction with Noven s post-vest termination information. We estimate the volatility of common stock by using a combination of both historical and implied volatility based on an equal weighting of each as management believes that marketplace participants would likely use the expected volatility in determining an exchange price for an option or SSAR. We are required to estimate forfeitures at the time of grant and revise those estimates in subsequent periods if actual forfeitures differ from those estimates. We use historical data to estimate pre-vesting forfeitures and record stock-based compensation expense accordingly. If factors change and we employ different assumptions for estimating stock-based compensation expense in future periods or if we decide to use a different valuation model, the future periods may differ significantly from what we have recorded in the current period and could materially affect our operating income, net income and net income per share. The Black-Scholes option-pricing model was developed for use in estimating the fair value of traded options that have no vesting restrictions and are fully transferable, characteristics not present in our stock option and SSAR grants. Existing valuation models, including the Black-Scholes and lattice binomial models, may not provide reliable measures of the fair values of our stock-based compensation. Consequently, there is a risk that our estimates of the fair values of our stock-based compensation awards on the grant dates may bear little resemblance to the actual values realized upon the exercise, expiration, early termination or forfeiture of those stock-based payments in the future. Stock options or SSARs may expire worthless or otherwise result in zero intrinsic value as compared to the fair values originally estimated on the grant date and reported in our financial statements. Alternatively, values may be realized from these instruments that are significantly higher than the fair values originally estimated on the grant dates, and reported in our financial statements. There currently is no market-based mechanism or other practical application to verify the reliability and accuracy of the estimates stemming from these valuation models, nor is there a means to compare and adjust the estimates to actual values.

Inventories

Inventories consist primarily of raw materials, work in process and finished goods for our commercial branded products and under certain circumstances may include pre-launch branded and generic products. Inventory costs include material, labor and manufacturing overhead. Inventories are stated at the lower of cost (first-in, first-out method, or FIFO) or market and as appropriate, we reflect provisions necessary to reduce the carrying value of our inventories to net realizable value.

We use a standard costing system to estimate our actual FIFO cost of inventory at the end of each reporting period. Historically, standard costs have been substantially consistent with actual costs. In addition, the allocation of overhead costs impacts our estimate of the cost of inventory. Total overhead costs, which were in excess of $30.0 million in 2008, include salaries and benefits, supplies and tools, equipment

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costs, depreciation and insurance costs and represent a substantial portion of our inventory costs. The allocation of overhead to inventory production costs and between and among our various products requires us to make significant estimates that involve subjective and often complex judgments, including, among other things, normal production capacity, the relationship between labor costs and overhead costs, the extent of labor that goes into producing products and the amount of overhead costs absorbed in manufacturing inventory. Any change in these assumptions could materially impact our recorded cost of products sold and stated inventory balances.

Our net inventory balances were $13.9 million and $12.1 million as of December 31, 2008 and 2007, respectively. We determine the market value of our raw materials, finished product and packaging inventories based upon references to current market prices for such items as of the end of each reporting period and record a write-down of inventory standard cost to market, when applicable. We periodically review our inventory for excess items, and we establish a valuation write-down based upon the age of specific items in inventory and the expected recovery from the disposition of the items. A provision is established for the estimated aged surplus, spoiled or damaged products, and discontinued inventory items and components. The amount of the provision is determined by analyzing inventory composition, expected usage, historical and projected sales information, and other factors. Changes in sales volume due to unexpected economic or competitive conditions are among the factors that could result in materially different amounts for provisions we establish. If our provisions prove to be inadequate, our inventories could be overstated or understated in any given period.

Novogyne Intangible Asset

As of December 31, 2008, Novogyne had a long-term intangible asset of $13.9 million related to the acquisition of the marketing rights to CombiPatch®. The amortization of this asset is included in cost of sales in Novogyne s financial statements. In accordance with SFAS No. 144, Accounting for the Impairment of Disposal of Long-Lived Assets, the CombiPatch® marketing rights are assessed for impairments whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. The impairment testing involves comparing the carrying amount of the asset to the forecasted undiscounted future net cash flows of the product. This analysis requires Novogyne to make a number of significant assumptions and judgments involving prescription trends, sales price, unit cost and product life cycle among many other factors. In the event the carrying value of the asset exceeds the undiscounted future net cash flows of the product and the carrying value is not considered recoverable, an impairment exists. An impairment loss is measured as the excess of the asset s carrying value over its fair value, calculated using a discounted future cash flow method. An impairment loss would reduce net income in the period that the impairment occurs. Events which could give rise to impairments include a number of inherent risks in the pharmaceutical industry and cannot be predicted. Further declines in CombiPatch® sales (whether as a result of the HT studies, competition in the category or otherwise) could require Novogyne to record an impairment loss related to these marketing rights. As a result of the significance of the CombiPatch® marketing rights, any such impairment loss could have a material adverse impact on Novogyne s and Noven s financial condition and/or results of operations.

Novogyne Loss Contingencies

Novogyne is required to establish accruals for certain loss contingencies related to litigation, including product liability claims. Novogyne accrues estimated legal fees and settlement costs in accordance with SFAS No. 5, Accounting for Contingencies. Accruals for

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product liability claims are recorded by Novogyne, on an undiscounted basis, when it is probable that a liability has been incurred and the amount of the liability can be reasonably estimated based on existing information. Novogyne includes estimated legal fees in accruals for product liability claims and makes adjustments as new information becomes available. Receivables for insurance recoveries related to product liability claims under Novogyne s third party insurance policy are recorded, on an undiscounted basis, when it is probable that a recovery will be realized. Novogyne s accruals and related receivables for product liability claims and other litigation accruals involve significant estimates, including estimates of incurred but not reported claims, estimates of cost per claim for both reported and unreported claims, allocation of cost between Noven, Novartis and Novogyne based on ownership dates and applicable indemnification and other agreements between them, estimates of insurance recoveries and judgments as to the recoverability of insurance receivables recorded. Since July 2004, Novartis, along with various other pharmaceutical companies, has been named in a number of lawsuits involving Novogyne s hormone replacement therapy products. Novogyne has established reserves in the amount of $9.0 million as of December 31, 2008 for expected defense and settlement expenses related to pending lawsuits as well as for estimated future cases alleging use of Novogyne s products. In addition, Novogyne has recorded an insurance receivable of $6.7 million, which is Novogyne s best estimate of the insurance coverage for recovery of claims.

Novartis controls and maintains the accruals associated with such litigation on behalf of Novogyne. The litigation accruals and estimated insurance recoveries are maintained by Novartis for its business as a whole and those accruals and recoveries relating to Novogyne are estimated by Novartis (based on claims specifically attributable to Novogyne s products and Novogyne s insurance policies). Based on an analysis of the underlying data, the amounts recorded by Novogyne represent Novartis best estimate of litigation accruals and estimated insurance recoveries relating to Novogyne. However, we cannot control Novartis analysis of the underlying data or its application of that analysis to Novogyne. Litigation and its outcome are inherently difficult to predict. Any change in the estimates of number of cases, cost per case, allocation of cost between Noven, Novartis and Novogyne, insurance recoveries and other assumptions could cause Novogyne s and Noven s financial results to significantly vary. Furthermore, if actual liability and insurance recoveries ultimately differ from that which has been recorded, Novogyne s and Noven s financial results in the period where the liability becomes payable and the insurance is recoverable could be materially affected by the adjustment of the liability and insurance recoveries.

New Accounting Standards

In May 2008, the Financial Accounting Standards Board (FASB) issued SFAS No. 16